

Exhibit E

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4 IN RE: ETHICON, INC. : Master File No.
5 PELVIC REPAIR SYSTEM : 2:12-MD-
6 PRODUCTS LIABILITY LITIGATION : MDL 2327
7 :
8 : JOSEPH R.
9 THIS DOCUMENT RELATES TO : GOODWIN
10 THE CASES LISTED BELOW : US DISTRICT
11 JUDGE

12
13 Mullins, et al. v. Ethicon, Inc.,
14 et al. 2:12-cv-02952
15 Sprout, et al. v. Ethicon, Inc.,
16 et al. 2:12-cv-07924
17 Iquinto v. Ethicon, Inc.,
18 et al. 2:12-cv-09765
19 Daniel, et al. v. Ethicon, Inc.,
20 et al. 2:13-cv-02565
21 Dillon, et al. v. Ethicon, Inc.,
22 et al. 2:13-cv-02919
23 Webb, et al. v. Ethicon, Inc.,
24 et al. 2:13-cv-04517
Martinez v. Ethicon, Inc.,
et al. 2:13-cv-04730
McIntyre, et al. v. Ethicon, Inc.,
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Oxley v. Ethicon, Inc.,
et al. 2:13-cv-10150
Atkins, et al. v. Ethicon, Inc.,
et al. 2:13-cv-11022
Garcia v. Ethicon, Inc.,
et al. 2:13-cv-14355

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October 6, 2015
Deposition of Elaine Duncan
- - -

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2 Lowe v. Ethicon, Inc.,
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3 Dameron, et al. v. Ethicon, Inc.,
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4 Vanbuskirk, et al. v. Ethicon, Inc.,
 et al. 2:13-cv-16183
5 Mullens, et al. v. Ethicon, Inc.,
 et al. 2:13-cv-16564
6 Shears, et al. v. Ethicon, Inc.,
 et al. 2:13-cv-17012
7 Javins, et al. v. Ethicon, Inc., .
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8 Barr, et al. v. Ethicon, Inc., .
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9 Lambert v. Ethicon, Inc.,
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12 Harmon v. Ethicon, Inc.,
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13 Snodgrass v. Ethicon, Inc.,
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15 Matney, et al. v. Ethicon, Inc.,
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6 Bennett, et al. v. Ethicon, Inc.,
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8 October 6, 2015

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10 DEPOSITION OF ELAINE DUNCAN, taken
 pursuant to notice, was held at the law
11 offices of Nilan Johnson Lewis, PA, 120
 South Sixth Street, Suite 400, Minneapolis,
12 Minnesota 55402, commencing at 9:15 a.m. on
 the above date, before Barbara J. Carey,
13 Registered Professional Reporter and Notary
 Public in and for the State of Minnesota.

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Elaine Duncan

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Pursuant to Rule 34 of Elaine Duncan

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Elaine Duncan

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Request for Production of Documents: None

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Elaine Duncan

1 ELAINE DUNCAN,

2 After having been first duly sworn, was called as a
3 witness and testified as follows:

4 EXAMINATION

5 BY MS. FITZPATRICK:

6 Q. Good morning, Ms. Duncan. My name is Fidelma
7 Fitzpatrick, and before we get started today, I'm going to
8 go ahead and mark some documents and give you copies so
9 you have them with you for today.

10 A. Okay.

11 MS. FITZGERALD: So if we can mark as
12 Deposition Exhibit Number 1, it's the Notice of Deposition
13 itself.

14 (Whereupon, Exhibit 1 was marked.)

15 BY MS. FITZPATRICK:

16 Q. Let me mark this document as Exhibit 2 and ask
17 you, Ms. Duncan, if you could identify that for me?

18 (Whereupon, Exhibit 2 was marked.)

19 THE WITNESS: This is my report.

20 BY MS. FITZPATRICK:

21 Q. Okay. And so I'm correct that what I've given
22 you is a complete copy of the report that you produced in
23 this consolidated case; is that right?

24 A. Yes, ma'am, and it includes my CV.

1 Q. Okay. And that's what you prepared for
2 Ethicon Company as their expert in this case; correct?

3 A. I updated my CV, yes.

4 Q. Okay. Do I have the most updated copy of your
5 CV?

6 A. Yes, ma'am.

7 Q. Great. So you might want to hold on to that
8 because I'll probably be asking you some questions from
9 that.

10 A. That's fine.

11 Q. Now, Ms. Duncan, when is the last time you had
12 your deposition taken?

13 A. Many years ago. Probably 1980 sometime.

14 Q. Okay. So let me just go over a few of the
15 ground rules. I'm going to ask you just a series of
16 questions. If at some point you can't hear me or you
17 don't understand what I've asked, please feel free to let
18 me know. If at any point you need a break, you want to
19 stretch your legs, just let me know and we can easily take
20 a break. Otherwise, I'll probably keep going and try to
21 get through this as quickly and painlessly for all of us
22 as possible.

23 Do you have any questions for me about how the
24 deposition is going to run?

1 A. No, I think I'm in good hands.

2 Q. Okay. Great.

3 A. Thank you.

4 Q. Ms. Duncan, do you agree with me that a
5 medical device manufacturer has the responsibility to
6 design their product so as to minimize the risk of
7 injuries to patients?

8 A. I believe that's the goal of every medical
9 device company, yes.

10 Q. Okay. And do you agree with me that in order
11 to design a product to minimize the risk of injuries to
12 patients, a responsible medical device manufacturer has to
13 consider and understand the actual medical condition that
14 the device is intended to treat?

15 A. Medical device manufacturers, yes, must
16 understand the indication for use, as well as the intended
17 uses, yes.

18 Q. And they must understand the underlying
19 medical conditions themselves; correct?

20 A. Yes, to the extent that it is known.
21 Sometimes devices are treating conditions for the
22 underlying conditions not totally known.

23 Q. Okay. Well, how about for a responsible
24 medical device manufacturer who is making a product to

1 treat stress urinary incontinence? You'd agree with me
2 that that medical device company would need to fully
3 understand the medical condition of stress urinary
4 incontinence; correct?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: What I'd like to qualify
7 is that each individual patient can come to the device
8 with variations in their condition. I mean, sometimes it
9 is not responsible to know every possible condition
10 underlying that individual patient's condition, but as a
11 general rule, it's true; we try to understand the majority
12 of the patients and what conditions they come to the
13 operating room with.

14 BY MS. FITZPATRICK:

15 Q. Okay. So fair enough. So putting aside
16 whether an individual patient, you'd agree with me that a
17 medical device manufacturer making a product to treat
18 stress urinary incontinence would need to know and
19 familiarize themselves with what's available in the
20 medical literature concerning the condition; correct?

21 A. With respect to my previous comment, yes.

22 Q. Okay. And you'd agree with me that a medical
23 device manufacturer that's designing a product designed to
24 treat stress urinary incontinence would need to understand

1 the treatment, alternate treatment methods that are
2 already on the market or available to patients at that
3 time; correct?

4 A. Let's go back over that one more time. That
5 was kind of a lengthy question.

6 Q. Okay. It was probably a bad question. Let me
7 see if I can do a better job with that.

8 You agree with me that a medical device
9 manufacturer who is making a product to treat stress
10 urinary incontinence would need to be aware of and
11 familiar with alternate treatment methods for that
12 underlying condition before making a product; correct?

13 A. Actually, may I say, in addition to what may
14 be available at the time of the design and development,
15 they, most typically, continue to monitor alternate
16 therapies.

17 Q. Okay. Great. And you would agree with me
18 that a medical device manufacturer making any kind of
19 medical device must consider and understand the anatomical
20 location where that device is going to be implanted;
21 correct?

22 A. That's a reasonable requirement, uh-huh.

23 Q. Okay. And you'd agree with me they also must
24 consider the length of time that the device is intended to

1 be left inside the patient's body; correct?

2 A. Obviously, if it's an indicated use as a
3 permanent implant, then they would need to know that it is
4 intended as a permanent implant.

5 Q. Okay. And you agree with me, to follow up on
6 that, that there are differences and different
7 considerations for medical devices that are left
8 permanently inside the body as opposed to medical devices
9 that are used temporarily or transitorily in the body;
10 correct?

11 A. Even the biocompatibility requirements have us
12 identify the length of intended use, like less than
13 30 days, more than 30 days, et cetera. So that's a
14 general condition we apply for design and development.

15 Q. Okay. And when -- a responsible medical
16 device manufacturer is making a medical device, it's
17 necessary that they consider and understand the actual
18 materials that they're going to use in that device;
19 correct?

20 A. It would be a requirement to understand the
21 materials, yes, qualify -- my term is qualify them.

22 Q. Your term is qualify, okay.

23 And you agree with me that a medical device
24 manufacturer should understand how the body can react to

1 the medical device that's been implanted; correct?

2 A. Try that again. I got distracted, I'm sorry.

3 Q. Sure. You'll agree with me that a medical
4 device manufacturer should understand how the body can
5 react to a medical device that's been implanted; correct?

6 A. How the body can react, certainly. It's part
7 of the biocompatibility.

8 Q. And you also agree with me that a medical
9 device manufacturer should understand and consider how the
10 device itself can react to the body; correct?

11 A. How the device itself can react?

12 Q. Correct.

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I'm struggling with how
15 that's different from the previous question.

16 BY MS. FITZPATRICK:

17 Q. So the previous question was the body's
18 response to the device, and now I'm asking the corollary
19 to that, which is the device's response to the body.

20 So you'll agree with me it's important to know
21 whether the device can deteriorate over time; correct?

22 A. We consider that as a part of the
23 biocompatibility and qualification of materials.

24 Q. And you'll agree with me it's important to

1 know that -- if the device can break down or stop working
2 after a certain period of time; correct?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: I'm sorry, stop working,
5 like in a battery, or what are you referring to?

6 BY MS. FITZPATRICK:

7 Q. No, I'm talking about a permanently-implanted
8 medical device.

9 A. Like a pacemaker, or what do you mean?

10 Q. Any kind of medical device. You need to know
11 what the lifecycle of that product is; correct?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I -- the life --
14 "lifecycle" is a term of art in compliance and quality
15 that has a broader meaning than --

16 BY MS. FITZPATRICK:

17 Q. Okay.

18 A. -- I think you're trying to use for it.

19 Q. Probably. I'm not using it as a term of art.
20 I'm just -- you need to know how long a device is going to
21 last when it's in the body; correct?

22 A. Many medical devices are permanent implants,
23 but we don't know how long they'll last in each individual
24 patient.

1 Q. Okay. And let me just clarify, when I'm
2 asking you questions today, I'm not asking you questions
3 about individual patients. I'm talking about your
4 generalized body of knowledge.

5 So the medical device manufacturer should
6 know on average or try to figure out on average how
7 long its medical device is going to last or work in the
8 body.

9 You agree with me on that; right?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Again, it's not always
12 possible to know when, for example, when the first
13 artificial hip was put in, I don't know that anybody
14 knew exactly how long that particular design would stay
15 in the body. We try to make them as good as we can, but
16 since disease conditions are progressing in many cases and
17 other conditions are taking place, as well, an individual
18 implant's life, or even a specific model of an implant,
19 we may be able to predict some modes of failure, but
20 the total lifespan in a human, it's not always known.

21 BY MS. FITZPATRICK:

22 Q. Okay. Well, let me pick up on something you
23 said.

24 You'll agree with me, though, that a medical

1 device manufacturer has a responsibility to make a device
2 as safe as it possibly can; right?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: Within reason, yes.

5 That's right.

6 BY MS. FITZPATRICK:

7 Q. And that's -- when you say "within reason,"
8 that's what's feasible, what's --

9 A. If you made it so safe that it couldn't
10 function.

11 Q. Okay.

12 A. You know, there's a limit because some
13 functionality is required.

14 Q. Okay.

15 A. And that's what might fail. So obviously,
16 you have constraints. You have design constraints,
17 yes.

18 Q. Okay. So fair enough. So assuming that
19 functionality remains constant, you'll agree with me that
20 a medical device manufacturer has the obligation to make a
21 product as safe as is feasible; correct?

22 A. As safe as feasible, yes.

23 Q. Now, the report that I've marked as Exhibit
24 Number 2 in here is the report that you produced in this

1 case on behalf of Ethicon; correct?

2 A. Yes, ma'am.

3 Q. And you understand that the product that's at
4 issue in this case is the TVT retropubic device with
5 mechanically-cut mesh; correct?

6 A. I was not specifically limited to that in my
7 report.

8 Q. Okay. Do you -- were you told by Ethicon or
9 by anyone that the patients who are the plaintiffs in this
10 case have TVT retropubic devices with mechanically-cut
11 mesh, specifically?

12 A. No, we didn't discuss the patients, you know.
13 The ground rules, my scope.

14 Q. Uh-huh.

15 A. Was what I would call due diligence of the
16 development and the compliance of the product of family of
17 TVT up to but not including TVT-O, so I was looking at a
18 timeline.

19 Q. What?

20 A. TVT-O, dash O. In a timeline, since I stopped
21 at that point. So I was not constrained strictly to the
22 mechanical cut.

23 Q. Okay. So your report contains conclusions and
24 opinions that apply to the TVT retropubic mechanically-cut

1 and the TVT retropubic laser cut; is that right?

2 A. Well, frankly, I had to because Ms. Wilson's
3 had included the laser cut in her opinion, so I,
4 obviously, had to consider that, as well.

5 Q. Okay. And you understand that Ms. Wilson's
6 report made a distinction between the TVT-R mechanical cut
7 and the TVT-R laser cut. I'm just asking, did you make
8 that same distinction in your report?

9 A. Where it was appropriate.

10 Q. Okay. Well, I'm going to be asking you a
11 series of questions today, and I want to ask you very
12 specifically about the TVT-R mechanical cut because that's
13 the product that the plaintiffs in this case have been
14 implanted with; okay?

15 A. I wasn't aware of that, okay.

16 Q. And if at some point you need to qualify or
17 you want to let me know that you're including a laser cut
18 in that or you have to include laser cut or you've gone to
19 the TVT-O, can you just make sure to let me know? Because
20 otherwise, I'm going to be talking about this TVT-R
21 mechanical cut.

22 MR. DAVIS: I'll object to form.

23 THE WITNESS: As long as you tell me
24 when you're referring to mechanical, I'll stay within that

1 boundary, as well.

2 BY MS. FITZPATRICK:

3 Q. I'm going to be referring to mechanical
4 throughout the deposition, so that's the product that I'm
5 going to be focusing on. So I just want to let you know
6 that, and if you need to deviate from that, you certainly
7 can. I just want to know that that's what's happening so
8 you and I are on the same page with what we're discussing;
9 okay?

10 A. Okay.

11 Q. Now, do you believe, based on your review of
12 the documents that you've looked at, that Ethicon
13 appropriately designed the TVT-R mechanical-cut device?

14 A. Well, what I have to clarify for you is the
15 original design was by Dr. Ulmsten, and the qualification
16 of the design was by Ethicon subsequently. But the
17 original design, as you phrased it in your question, was
18 not by Ethicon.

19 Q. Okay. Do you believe, based on your review of
20 the documents that you've seen, that Ethicon appropriately
21 qualified the design of the TVT-R mechanical-cut product?

22 MR. DAVIS: Object to form.

23 THE WITNESS: Yes, ma'am, I do.

24

1 BY MS. FITZPATRICK:

2 Q. Is there anything that you saw in your review
3 of the documents in this case that led you to believe that
4 Ethicon overlooked or didn't properly consider something
5 when qualifying the design of the TVT-R mechanical cut?

6 A. Do I believe they overlooked anything?

7 Q. Overlooked or didn't properly consider
8 something.

9 A. Not to my knowledge.

10 Q. Okay. And do you believe, based on your
11 knowledge or experience, your training, that there was a
12 better way for Ethicon to qualify the design of the TVT-R
13 mechanical cut than it did?

14 A. Do I believe there was a better way? I looked
15 at the process that they went through in the qualification
16 from the standpoint -- from the point of view of -- well,
17 at the time of the original due diligence for licensing a
18 product through to a certain cutoff time for the
19 documentation, and I perceived the engineering and
20 the clinical trial data and the biomaterial testing data
21 were all consistent with knowledge and practice at the
22 time.

23 Q. Okay. So let me go back to my question -- and
24 I understand that's your opinion, and that's throughout

1 your report.

2 Do you think there was a better way that
3 Ethicon could have gone about qualifying the design of the
4 TVT-R mechanical-cut product?

5 A. Again, it was not my job to evaluate a better
6 way or to critique the engineering aspects. I was
7 looking at the process of how they went about it.
8 So I can't tell you in retrospect, either from my own
9 personal experience or what I read, that there was a
10 better way. Just, it's outside the scope of what I was
11 evaluating.

12 Q. Okay. So you don't have an opinion on that;
13 is that right?

14 A. I don't have -- I can't agree that there
15 is a better way. I don't say that I don't have an
16 opinion. What I'm saying is I can't agree that there was
17 a better way.

18 Q. Okay. Well, then let me ask the flip of that.
19 Do you believe that Ethicon used the best
20 practices possible in qualifying the design of the TVT-R
21 mechanically-cut mesh?

22 A. With respect to that time frame, certainly,
23 yes.

24 Q. Okay. And sitting here today with the --

1 sitting here today with the benefit of hindsight, which of
2 course we do --

3 A. 20/20.

4 Q. -- always 20/20.

5 Is there anything that you would recommend
6 today to Ethicon that would have changed that design
7 qualification back in the late '90s, early 2000s?

8 A. It's my conclusion that this device, based on
9 the clinical experience and the robust endorsement of this
10 device by the AUGS organization, and even the FDA, that I
11 would be foolhardy to try to suggest there's a better way
12 to make this product.

13 Q. Okay. So let me ask -- because I think we're
14 maybe talking about two different things here.

15 AUGS was not involved in the design process or
16 the qualification of the design of the TVT-R
17 mechanically-cut mesh; correct?

18 A. Physicians were certainly incorporating their
19 ideas, yes.

20 Q. Okay. But you specifically mentioned the
21 AUGS.

22 A. Uh-huh.

23 Q. And you'll agree with me that AUGS had nothing
24 to do with the qualification of the design of the TVT-R

1 mechanically-cut mesh back in the late 1990s and early
2 2000S; correct?

3 A. AUGS would not have been. They're not --
4 they're physicians and it's a physicians' organization.

5 What I was trying to say is the proof of the
6 pudding is the product we have today, and so that is
7 the judge -- judgment of the design, in my opinion.

8 Q. But you're not a medical doctor; correct?

9 A. No.

10 Q. And you've never done clinical trials in
11 patients; correct?

12 A. I've managed clinical trials, but I've never
13 done them, no.

14 Q. You've never done them.

15 And you've never treated a woman who has SUI;
16 correct?

17 A. That's right.

18 Q. And you're not a member of AUGS; correct?

19 A. That's right.

20 Q. And you don't have any anatomical or special
21 medical training in the TVT device and its use in women;
22 correct?

23 A. I couldn't implant one, no.

24 Q. Okay. So you're not here to talk -- and

1 you're not qualified to talk -- about the clinical, the
2 medical risk and benefit of the TVT-R mechanically-cut
3 device today; correct?

4 A. But ma'am, you asked me -- I think if you go
5 back to the question, it was "Would there be a better way
6 of doing it?" And I have to say, again, that the proof is
7 in the pudding, that when we look at a device, which is
8 functioning as intended and safe, I would not recommend to
9 a company to go back and redesign it.

10 Q. And perhaps we're talking about something
11 different. I think this is what I'm trying to get at with
12 you.

13 A. Okay.

14 Q. I'm not talking about going back and
15 redesigning.

16 A. Okay.

17 Q. There's a process that every company has to go
18 through when designing a medical device; correct?

19 A. They vary, but as a general framework, we
20 currently do, yes.

21 Q. Okay. And the reason the process is in place
22 is ultimately to ensure patient safety; correct?

23 A. That's the goal, yes.

24 Q. And you believe that it's important for

1 companies to go through the process of doing a risk
2 analysis on medical devices prior to putting them on the
3 market or selling them on the market; correct?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: You have to have a context
6 for that statement. So today, it is the common practice.
7 I was working in the medical device industry in the '70s
8 and '80s, and we certainly were not constricted to design
9 control and review at that time, and we made perfectly
10 good devices then, like the St. Jude heart valve.

11 BY MS. FITZPATRICK:

12 Q. Okay. Well, maybe if we back up a little bit,
13 we can get on the same page, because I think we might be
14 talking past each other here.

15 A. Okay.

16 Q. You agree with me that when you're doing
17 hazard analysis and risk assessment, it's important to
18 take a total product lifecycle view of risk management;
19 correct?

20 A. That's what we're instructed to do now with
21 the standards, yes.

22 Q. And you agree with that?

23 A. Yeah, I would agree with that.

24 Q. And you would agree with me that when you're

1 looking to do a risk analysis, you should look at a hazard
2 which should be thought of as a failure of the device to
3 meet expected performance requirements; is that right?

4 A. When we're doing a hazard analysis, that's the
5 exercise we take.

6 Q. Okay.

7 A. We take the input requirements and project as
8 a what if it failed to meet that requirement, would there
9 be a hazard associated with it? That's how that exercise
10 is done.

11 Q. Okay. This is what I want to get to.

12 You agree that it's important to employ a
13 systematic and analytical method to document potential
14 hazards; correct?

15 A. That's what we do now, yes.

16 Q. And that's the process that I'm talking about.

17 A. Okay.

18 Q. And that's something that you believe that a
19 responsible medical device manufacturer should do in order
20 to design the safest medical product that it can; correct?

21 A. That's what's proven out over time to be a
22 very useful exercise. It's not the only way to get a
23 product done.

24 Q. Okay. And you agree with me that sometimes a

1 product developer wants to phone it in; correct -- that
2 they don't follow a process; correct?

3 A. It's possible that anybody can try to do that.

4 Q. Okay. And you agree with me that both the
5 potential customer and the medical device developer will
6 suffer from any shortcuts that a medical device
7 manufacturer takes in this process of hazard analysis and
8 risk assessment; correct?

9 MR. DAVIS: Object to form.

10 THE WITNESS: It may occur. It isn't a
11 foregone conclusion. It's a possibility.

12 BY MS. FITZPATRICK:

13 Q. Okay. You say it may suffer or it will
14 suffer?

15 A. It could suffer.

16 Q. Okay. And that's a little different from what
17 you said before; correct?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: I don't know that it's
20 different.

21 BY MS. FITZPATRICK:

22 Q. Do you remember writing a book, "The Potential
23 Customer and the Medical Device Developer Will Suffer From
24 Any Shortcuts"?

1 A. That was an article, and that was the context
2 because that was a training article, and I was trying to
3 train people in the textile industry who might be
4 considering getting into the medical industry.

5 Q. Okay. Is that sentence true or not?

6 A. I think it's true.

7 Q. Okay. And you also agree that if a company
8 skips working meetings and just passes around, basically,
9 a spreadsheet to have people sign off on it, that that can
10 spell disaster; correct?

11 A. If -- as you said, if they phone it in, it can
12 be a problem because they need the interaction with one
13 another.

14 Q. Okay. And so, as part of your preparation for
15 today's deposition, can you tell me what documents related
16 to working meetings that you looked at related to
17 Ethicon's qualification of the design of the TVT-R
18 mechanical cut?

19 A. As I previously said, Ethicon was not
20 responsible for the original design. What I looked at
21 was --

22 Q. Okay. Let me --

23 MR. DAVIS: Are you finished with your
24 answer?

1 BY MS. FITZPATRICK:

2 Q. I think you missed part of what I asked you.

3 MR. DAVIS: Were you through with your
4 answer?

5 THE WITNESS: I suggest you start over
6 because you interrupted my train of thought.

7 BY MS. FITZPATRICK:

8 Q. Sure. And I'm sorry about that.

9 As part of your preparation for today's
10 deposition, can you tell me what documents you looked at
11 that related to working meetings related to Ethicon's
12 qualification of the design of the TVT-R mechanical cut?

13 A. As I previously said, the design was already
14 in the clinic. It had already gone through the normal
15 design process when Ethicon came on the scene. The
16 product was already in patients.

17 Typically, clinical evaluation is the last
18 stage of the design development process. So when Ethicon
19 came on the scene, they did a due diligence to qualify the
20 design for their intended purposes, which was an
21 international sales of the device. So that's what the due
22 diligence process was, and I reviewed the original due
23 diligence documents that Ethicon did before they signed
24 the agreement to license the product.

1 Q. Okay.

2 A. That was the review process --

3 Q. Uh-huh.

4 A. -- that was conducted. It was -- it's
5 different than the design review process we do today.

6 Q. Uh-huh.

7 A. Okay.

8 Q. Okay. What documents have you looked at that
9 concerned working group meetings by Ethicon when they look
10 to qualify the design -- which is your term -- of the
11 TVT-R mechanical? I just want to know what those are so I
12 can take a look at them.

13 MR. DAVIS: Object to the form. You can
14 answer.

15 THE WITNESS: I believe there were
16 several design checklists. There were checklists for the
17 due diligence activities, and that included various
18 requirements, as what a checklist is. Their due diligence
19 was to organize the information and review the
20 information, and those were, as I recall, several
21 review -- there was certainly at least one, if not two,
22 review meetings where this was taking place.

23 BY MS. FITZPATRICK:

24 Q. Okay. I want to talk, not about the

1 spreadsheets and the checklists, I want to talk about the
2 actual what you have called working meetings.

3 What working meetings did Ethicon have at the
4 time it qualified the design of the TVT-R mechanical?
5 What did you look at?

6 A. Do you want me to bring those documents out?

7 Q. Sure, that would be great.

8 MR. DAVIS: I don't know that we have
9 them all. Do you have some -- you can refer to your
10 report.

11 THE WITNESS: Let me just look at this.

12 BY MS. FITZPATRICK:

13 Q. Yeah, and I'm just looking for the working
14 group meeting, not the checklist. We'll get to some of
15 those later, the specific meetings.

16 A. The checklists were reviewed at the meetings.

17 Q. Okay. Tell me how you know that.

18 A. I can read the documents.

19 Q. Tell me the document. That's all I'm asking
20 for.

21 A. Well, again --

22 Q. You can take a look through it. Take your
23 time. Take a look through it if you want.

24 MR. DAVIS: They may not all be listed

1 in her report, either.

2 THE WITNESS: Well, here's a start.

3 BY MS. FITZPATRICK:

4 Q. Just if -- if you can just tell me where you
5 are in your report.

6 A. Go to page 15.

7 Q. Okay. I'm with you.

8 A. So if you look at the Bates number on the
9 footnote.

10 Q. Which footnote?

11 A. 18.

12 Q. Okay.

13 A. That was one of the citations in the report.

14 Q. And you believe that the document cited in
15 Footnote 18 will reflect these working group meetings by
16 Ethicon when qualifying the design of the TVT-R mechanical
17 cut?

18 A. Well, certainly they reflect the results.
19 Sometimes meetings have minutes or reports after the
20 meetings, so I take this as a reflection of the work they
21 did. Without double-checking this Bates number, I can't
22 tell you if there's other documents that I would call to
23 your attention. I can probably get you some of those
24 later, some numbers. I don't know if this is a complete

1 list.

2 Q. Okay. So all I'm -- I don't want there to be
3 any confusion in the record.

4 Sitting here right now, you can't point me to
5 a particular Bates number of what you did, but you might
6 look further, and you'll let me know later if you find
7 anything else that supports --

8 A. It's not something I can recall, all of the
9 Bates numbers.

10 Q. Completely understandable. I can't either.

11 A. I recall at least four or five that I was
12 looking at in that timetable.

13 Q. Do you recall seeing any meeting minutes of
14 meetings that Ethicon conducted to qualify the design of
15 the TVT-R mechanical cut?

16 A. Again, I can't recall the numbers, and I
17 recall that there were.

18 Q. You recall that there were?

19 A. That's my recall.

20 Q. And do you also believe that there --

21 A. Again, I wouldn't necessarily characterize
22 them as minutes.

23 Q. Okay. So --

24 A. It could be a report from a meeting. I

1 believe they represented in the documentation that they
2 had had meetings, and these were reports of those
3 meetings.

4 Q. Okay. So let me -- let me start with the
5 minutes.

6 Do you recall whether you saw any actual
7 meeting minutes related to the qualifying of the design of
8 the TVT-R mechanical cut?

9 A. I would want to look at the document before I
10 characterized them as minutes.

11 Q. Okay. And then I'm going to ask you a second
12 question.

13 Do you remember seeing any meeting reports
14 that documented what had happened in any working meetings
15 that Ethicon had concerning qualification of the design of
16 the TVT-R mechanical cut?

17 A. Again, the qualification at that juncture for
18 the due diligence was different than a design
19 qualification.

20 Q. Yeah, I understand.

21 A. Okay.

22 Q. I'm asking you with what Ethicon did.

23 A. Right. Okay.

24 Q. Do you recall seeing any meeting -- reports of

1 meetings or minutes -- I don't want to say "minutes."

2 A. I would say there was some effort, and I
3 can't say if it was a single document report for a
4 single meeting, because there were multiple activities
5 and multiple meetings.

6 Q. Okay. But sitting here right now, you just
7 don't know which Bates numbers those would be?

8 A. I don't know the Bates numbers off the top of
9 my head, I'm sorry.

10 Q. Okay. But if it was something that Ethicon --
11 that you saw in the Ethicon documents, you would have
12 considered that to be important in continuing this hazard
13 analysis and risk assessment of the TVT-R; correct?

14 MR. DAVIS: Object to form.

15 THE WITNESS: Wait a minute. That's
16 mixed messages there.

17 BY MS. FITZPATRICK:

18 Q. Okay.

19 A. The first part of it, what did you say?

20 Q. I don't know. It's not there.

21 A. You want to ask it again?

22 Q. Yeah, let me ask it again. I'm talking about
23 Ethicon generally.

24 If you had seen meeting minutes or you had

1 seen reports of meetings concerning the qualification of
2 the TVT-R mechanical-cut design, that's something that you
3 would have considered important to take a look at in
4 connection with your report here; correct?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: It's out of context,
7 ma'am.

8 BY MS. FITZPATRICK:

9 Q. Okay. Tell me how.

10 A. You were talking previously about the due
11 diligence and license and now you broadened it.

12 Is that your intention?

13 Q. I think that I was always talking about the
14 qualification of the design. That's always been my
15 question.

16 So what I'm asking you is you have written
17 before that you believe that working meetings are
18 important when conducting any kind of hazard analysis and
19 risk assessment on a particular medical device; correct?

20 A. The article that you're referring to there and
21 what I was instructing and training people who might read
22 my article about was the efforts that we do
23 contemporaneously today. This is our expectations from
24 standards and regulations today. When I was examining the

1 due diligence of Ethicon through the phases and brought up
2 refinement for mechanical cut, I looked at their
3 documentation with respect to the requirements upon them
4 then. It's very important to keep a temporal context when
5 we're looking at these documents.

6 Q. Okay. When do you believe it became a
7 requirement or important to conduct working meetings when
8 conducting hazard analysis and risk assessment? What's
9 the date for that?

10 A. I believe we started to see a recognition of
11 14971. It really didn't kick into medical device
12 companies in an active way until probably I'm going to
13 say 2000, 2003, in that time frame.

14 Q. Okay. So is it your testimony, just so I
15 understand it, that you believe that working meetings to
16 discuss hazard analysis and risk assessment are required
17 from 2003 on but they weren't required before 2003?

18 A. Understand, there's practices that go on. So
19 14971 has been an evolving document, as was EN 1441 was
20 the core document. When that document was in place,
21 I would have to tell you that in my experience, many
22 companies would exercise risk analysis with one or two
23 people. They didn't have group meetings and team
24 meetings like they do now, and it was after 2007 when

1 that standard became more accepted across the U.S. and
2 internationally that people began to practice hazard
3 analysis group meetings, sometimes not just one meeting,
4 but multiple meetings. It would happen collectively.

5 I have chaired such meetings, frequently, for
6 companies where they were learning the process, and
7 oftentimes, it would be iterative and sometimes quite
8 contentious. And so, it was a learning experience back
9 then. It wasn't a garage door coming down and everybody
10 did everything after that point in time.

11 Q. Okay. So is it fair to say it's your position
12 that Ethicon wasn't required to do working group meetings
13 concerning its hazard analysis and risk assessment of the
14 TVT-R mechanical cut prior to 2003?

15 A. Required by whom?

16 Q. You said "required." I -- I'm going to get to
17 the question of required by whom, but I'm using your
18 terminology there.

19 A. Well, that's what I'm saying. No one was
20 requiring group meetings in the context of the way you
21 asked the question.

22 Q. Okay. And then you believe that from 2003
23 on -- from 2003 to 2007, if I'm understanding you
24 correctly, these types of group meetings were phased in

1 through a learning process; is that correct?

2 A. I believe that's correct. I believe there
3 were a number of training programs. FDA had put out some
4 guidance documents. It -- it's kind of a group think.
5 We refer to that as best practices, and so oftentimes
6 people will go to a regulatory training or quality
7 training meetings and they start to adopt that and bring
8 that back, and the quality of the document starts to
9 improve when they have broader teams.

10 Q. Okay.

11 A. So that -- I didn't mean, when I said "require
12 it," I didn't mean to say that there was a sudden
13 lightning bolt and everybody after that point in time
14 behaved a certain way. It was an evolution.

15 Q. Okay. Fair enough. And then post from 2007
16 on, this is standard and this is an accepted best
17 practice, that you do group meetings to do risk assessment
18 and hazard analysis?

19 A. I think that's best practices. Even today,
20 it's best practices. It's not -- I can't say it's
21 100 percent of the time.

22 Q. And you agree that those types of group
23 meetings, regardless of when they were phased in, do --
24 I'll get your -- do help improve the quality of the

1 documentation --

2 A. Of the analysis.

3 Q. -- of the analysis of everything that is --

4 A. Because you try to have a broad perspective of
5 the team.

6 Q. Okay. How broad was the team that Ethicon
7 used --

8 MR. DAVIS: Object to the form.

9 BY MS. FITZPATRICK:

10 Q. -- to qualify --

11 MR. DAVIS: I apologize. I didn't
12 realize that was a pause.

13 BY MS. FITZPATRICK:

14 Q. Let me start all over again.

15 A. He's too fast.

16 Q. How broad was the team that Ethicon used to
17 qualify the design of the TVT-R mechanical cut?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: Again, your -- we have to
20 go back to the design was completed, and in the clinic
21 when Ethicon came on the stage as due diligence, for its
22 due diligence. So I wouldn't characterize that in that
23 way. They were not applying the rules we have today when
24 they were doing due diligence.

1 BY MS. FITZPATRICK:

2 Q. Okay. So let me -- I don't want us to be
3 talking past each other. I'm using "qualified the
4 design." I'm using that phrase because that's the phrase
5 that you told me. You told me that's what Ethicon went
6 through when it acquired the TVT-R mechanical cut. They
7 qualified it; is that correct?

8 A. Are we jumping over to the acquisition phase?

9 MR. DAVIS: I object.

10 BY MS. FITZPATRICK:

11 Q. I'm talking your phrase -- why don't you tell
12 me what you meant by "qualifying the design"? Maybe
13 that's a better way to do it so we're talking about the
14 same thing.

15 A. Whenever there's a change to a design, some --
16 well, if I can back up completely.

17 So the design control and review requirements
18 within the FDA regulations look for you to evaluate --
19 well, first to have a design plan, to evaluate input
20 requirements, to assess hazards associated with failing to
21 meet those input requirements; from the hazard analysis
22 and the input requirements, to develop a verification and
23 validation plan, and to then execute those, review those.
24 You may have to circle back and consider your design input

1 requirements again.

2 And then you do a design transfer to
3 manufacturing. And again, in that phase, you may have to
4 circle back again. So it can be an iterative process.
5 That is an original design qualification process.

6 When we are considering acquiring a design
7 from someone else, we may do a truncated review of the
8 documentation that went with their development process,
9 and when we do that, we have to be mindful of the time and
10 expertise. So time in terms of chronological time, but
11 also the expertise that went into the original design in
12 the first place.

13 Does that help? That's what I would call a
14 design qualification.

15 Q. Of course it gives me 1,000 more questions,
16 but I'll stick with this for right now.

17 A. I'm sorry, I'm trying to be helpful.

18 Q. No, no, no. Thank you. I appreciate that.

19 The review of the documents -- Ethicon
20 undertook a review of the documentation from Medscand of
21 the TVT-R mechanical cut; correct?

22 A. Are you speaking of the due diligence phase?

23 Q. Well, I'm going to --

24 A. Because when I did my due diligence, I

1 basically, went in layers. So I evaluated an event, an
2 event, an event; okay? So when you ask me a question,
3 I have to be in the context of time and place and
4 people.

5 Q. Okay.

6 A. Okay? That's how I did the work.

7 Q. This is way more confusing, and maybe I'm very
8 simplistic in terms of how I deal with it, so --

9 A. And I've been accused of being overly
10 detailed.

11 Q. Let me go back.

12 You just gave me a good instruction on the
13 design qualification process; correct?

14 A. Of a new design.

15 Q. Of a new design?

16 A. Uh-huh.

17 Q. And then, I believe that you told me that when
18 you acquire a product, a company can do a truncated review
19 of the documentation that was provided by the company that
20 originally designed the product; correct?

21 A. That's correct.

22 Q. And so in this case, it would be Ethicon that
23 would be doing the review of the documentation from
24 Medscand when it acquired the TVT-R mechanical cut;

1 correct?

2 A. So we're speaking of acquiring now?

3 Q. Uh-huh.

4 A. And the question was?

5 Q. The question was, just simply, how many people
6 did Ethicon have involved in the review of the
7 documentation that it did of the Medscand documents at the
8 time that it acquired the TVT-R mechanical cut?

9 A. I didn't count them all. I know we're
10 speaking of more than dozens. I just recall seeing
11 many people involved in that process.

12 Q. Okay. So we have dozens of people involved in
13 that process?

14 A. At least, yeah.

15 MR. DAVIS: Object to the form.

16 BY MS. FITZPATRICK:

17 Q. Let me ask you this, then.

18 Did you -- going back to the question of
19 working groupings, did you see any documentation that
20 those dozens of people met to discuss, review, look at,
21 consider collectively the documentation that had been
22 provided by Medscand at the time that Ethicon acquired the
23 TVT-R mechanical cut? Just, did you see that?

24 MR. DAVIS: I object to form. She did

1 not say "dozens," plural. That was your term. She said
2 "at least a dozen."

3 THE WITNESS: I said "at least a dozen."

4 I don't remember an exact number.

5 BY MS. FITZPATRICK:

6 Q. I'm sorry, let me make sure I've got the right
7 answer.

8 You said, "I didn't count them all. I know
9 we're speaking of more than dozens."

10 Is that --

11 A. A dozen. What -- when you look at the
12 documentation of the asset acquisition review, there
13 were the people whose names were mentioned in the memos,
14 but then there are people behind those memos and the
15 work that was going on to review those products and
16 conduct that activity.

17 For example, in an asset acquisition phase,
18 they were looking at good -- between the due diligence for
19 licensing and up to the phase of asset review from a
20 purchase, they were conducting audits, and they were
21 auditing to the Good Manufacturing Practices from 1976,
22 and they were anticipating the requirements that would be
23 required for the new standards and regulations that were
24 coming out. So this was a continuum.

1 For due diligence, they did a certain group of
2 work. They anticipated additional work if they were going
3 to acquire it. It wasn't a foregone conclusion that they
4 would acquire it, so they were doing various exercises to
5 understand the status of the records at the time.

6 Q. Okay. I just want to -- I don't want to --

7 A. You keep talking about group meetings.

8 Q. Because that's what my question is. So you're
9 answering a different question.

10 A. Okay.

11 Q. Here's the first thing.

12 I asked you how many people at Ethicon --

13 A. Uh-huh.

14 Q. -- were involved in the review of the
15 documentation from Medscand on the TVT-R mechanical cut,
16 and I think we had a little miscommunication. I thought
17 you said "dozens." Your attorney said that you didn't
18 mean it.

19 Just do you know how many people, just to
20 clarify that for me?

21 A. Ma'am, I would have to pull the documents
22 and count their heads. I don't recall an exact
23 number.

24 Q. So you don't know. That's okay.

1 A. It was a team of people. It's not that I
2 don't know. I don't recall.

3 Q. Okay. Do you want to take a look at your
4 report and tell me where I could find that information?

5 MR. DAVIS: Object to form.

6 THE WITNESS: I'm not sure we're going
7 to find it in any one Bates-numbered document. I'll have
8 to pull the whole record of the due diligence of the --
9 from the time of the due diligence of the license and the
10 due diligence of assets.

11 MR. DAVIS: Let me just say this
12 to make sure it's clear. We'd be happy, if you'd
13 like, to go off the record and let her -- I've got the
14 documents if you want her to take the time to look at
15 them.

16 MS. FITZPATRICK: Sure, if you want to
17 go off the record and take a look at that, I'm happy to do
18 that, give you some time. I just want to make sure we're
19 on the same page. Take a break.

20 (Whereupon, a recess was taken from
21 10:04 a.m. to 10:05 a.m.)

22 MS. FITZPATRICK: Before we took the
23 break, there had been some misunderstanding or
24 miscommunication about whether we're talking about dozens

1 of people or a dozen people. I'm just looking for a
2 ballpark estimate, and I just was looking for the
3 documents that you were relying on for that. That's all.
4 I'm not looking for anything more than that.

5 THE WITNESS: Okay. If I get over a
6 dozen, do you want me to stop?

7 BY MS. FITZPATRICK:

8 Q. Sure. That's fine. Just give me a ballpark
9 figure and give me the Bates numbers, and we'll deal
10 with that.

11 A. Okay. From due diligence through assets?

12 Q. Yes.

13 A. Okay. I can do that.

14 MR. DAVIS: I do want to say one thing
15 while we're still on the record, though.

16 I mean, my position is, unless I get
17 countermanded by Phil, that this time will count toward
18 her seven hours.

19 MS. FITZPATRICK: We just went off the
20 record.

21 MR. DAVIS: No, we're on the record.

22 MR. COMBS: And we'll go back on the
23 record.

24 MR. DAVIS: We're on the record; aren't

1 we?

2 THE REPORTER: Right now.

3 MS. FITZPATRICK: If you want to take
4 the position that she doesn't know and she can't
5 identify --

6 MR. DAVIS: No, we're not taking that
7 position, but you know, she's not required to sit here and
8 regurgitate names and numbers.

9 MS. FITZPATRICK: Then you just say "I
10 don't know sitting here."

11 MR. DAVIS: Let's go off the record.
12 We're going to take a break for five minutes.

13 (Whereupon, a recess was taken from
14 10:07 a.m. to 10:12 a.m.)

15 BY MS. FITZPATRICK:

16 Q. Before we took our break, I think, Ms. Duncan,
17 I had asked if you had particular documents that you were
18 relying on or looking at for your opinion that there were
19 either a dozen or dozens or numerous people that were
20 involved in the review, as you described it, of the
21 documentation from Medscand about the design of the TVT-R
22 mechanical cut at the time it was acquired by Ethicon;
23 correct?

24 A. Part -- partly correct. They reviewed broader

1 than the design. They reviewed the entire quality
2 program.

3 Q. Okay.

4 A. As it existed at that time. There were audits
5 to that effect.

6 Q. Okay. So we're talking about the design and
7 the quality program, and you have found documentation for
8 your opinions about the number of people or the general
9 number of people that were involved in that process;
10 correct?

11 A. We're still pulling that together for you, but
12 one document we found had at least 14 people named.

13 Q. Okay. And what document is that?

14 MR. DAVIS: Well, I'll read it off.

15 MS. FITZPATRICK: Yeah, that would be
16 great.

17 MR. DAVIS: The Bates number is
18 ETH.MESH09748308 through 385, and just, if it helps you,
19 Fidelma, that is the document that is -- the title on the
20 cover page is "Project Tomo (ph) Due Diligence Summary."

21 MS. FITZPATRICK: Okay.

22 MR. DAVIS: About the third -- fourth
23 page of the -- PDF page, that is a document that has a
24 list of all the team members at that time.

1 MS. FITZPATRICK: Okay. Great.

2 MR. DAVIS: Now, the question I have is
3 do you want a complete list? I mean it would take her
4 hours.

5 MS. FITZPATRICK: No, no, I'm not asking
6 her for a complete list. We had a -- Ms. Duncan said
7 "dozens." I asked her questions based on dozens. You
8 didn't think it was -- I'm just trying to make sure we're
9 on the same page with what we're talking about.

10 MR. DAVIS: You and the court reporter
11 may have thought she said "dozens." I thought I clearly
12 heard her say "At least a dozen."

13 MS. FITZPATRICK: It very well could be.
14 I just want to know which it is. I don't want -- I'm
15 not trying to trick her up here. I just want to know what
16 the answer is.

17 THE WITNESS: It's big. During the
18 asset acquisition -- and well, actually, during the
19 licensing phase, the Ethicon team, regulatory team,
20 submitted a 510(k), so that group is typically another
21 handful of people, you know, anywhere from one to five,
22 and in looking at some of those documents, I recall there
23 was more than one person involved in that process.

24 So when I am speaking of teams, I'm speaking

1 quite literally that there are not only more than a single
2 individual, that there may be more than a single team.

3 BY MS. FITZPATRICK:

4 Q. Okay. Fair enough. Now, let me ask you about
5 those teams or those groups of people.

6 A. Uh-huh.

7 Q. Did you see, in your review of the documents
8 to your recollection, any minutes of any meetings with
9 those team members at that particular time?

10 A. I, again, have to clarify that I can't recall
11 that they called them minutes. There were reports of
12 meetings.

13 Q. Okay. So you looked at reports of meetings,
14 and those would be cited either in your report itself or
15 in your reliance list; is that right?

16 A. I believe so, yes.

17 Q. And sitting here right now, you can't point me
18 to which particular Bates numbers or ranges of documents
19 those are; can you?

20 A. Well, here's one on page 17. It says,
21 "Various reports in October 1999 summarized the status of
22 the due diligence activities." So that Bates number is
23 listed.

24 Q. Oops, I'm sorry, that's 32?

1 A. Actually, 32 is referring to 31, and 31 is a
2 long list of Bates numbers.

3 Q. Okay. So I can take a look at those and that
4 will be what you relied on for that portion of your
5 opinion; correct?

6 MR. DAVIS: Object to the form.

7 BY MS. FITZPATRICK:

8 Q. Did you rely on those for that portion of your
9 opinion?

10 MR. DAVIS: No, my objection was you're
11 trying to limit her to that. She's got reliances, as
12 well.

13 BY MS. FITZPATRICK:

14 Q. Did you rely on those for this portion of your
15 opinion? That's why you footnoted them; right?

16 A. Ma'am, what I typically did for the footnotes
17 was I would select the best examples, but I reviewed
18 thousands of pages.

19 Q. Okay. My only question was, in Footnote 31
20 and 32, you have listed a number of documents.

21 Did you rely on those documents for the
22 opinions that you have set forth in those sentences?

23 A. Those I would have to say in part, but not
24 exclusively.

1 Q. Okay.

2 A. They're footnoted because they're significant.

3 If you look up above --

4 Q. All I want to know is if you relied on them?

5 MR. DAVIS: She didn't finish her
6 answer.

7 THE WITNESS: Paragraph 3, the last
8 sentence, is where that footnote begins, 31, and I'm
9 referring to the CE Mark Analysis by the notified
10 bodies, the QA and the RA due diligence that included
11 the design history files and other quality documentation.
12 That's the statement that those footnotes are referring
13 to.

14 So what I tended to do, is like you do a
15 literature article where you make a declarative statement.
16 You put a footnote to it. That's justification for that
17 statement. That doesn't mean those are the only documents
18 I looked at.

19 BY MS. FITZPATRICK:

20 Q. Okay. So all I was really getting at -- and I
21 think it's fairly simple -- if you've cited a document in
22 a footnote following the sentence, it's because you
23 believe that document -- not exclusively, not alone -- but
24 that document, in some way, supports the opinions you've

1 given?

2 A. Yeah, uh-huh.

3 Q. So if you could actually take a look at
4 Footnote 28 for me, please.

5 A. Do you want us to pull up the Bates number, or
6 what?

7 Q. No, I'm going to show you one. I'm going to
8 show you -- you've got Ethicon mesh 10186745.

9 Do you see that?

10 A. Uh-huh.

11 Q. And I'm going to give you the document that
12 contains that. We can mark this as Deposition Exhibit
13 Number 3, please.

14 (Whereupon, Exhibit 3 was marked.)

15 MR. DAVIS: Fidelma, there's a
16 typographical error -- Footnote 28 of the document that
17 she is handed is not the document that is referenced in
18 the report. It is -- there is a typographical error in
19 the report. It does say 10186745. It should be 1058.
20 The 1 should be a 5, and that is a typographical error.

21 THE WITNESS: Yes, I would not have
22 cited the Prolift.

23 BY MS. FITZPATRICK:

24 Q. Yes, that's -- let me just go through it.

1 Well, that's yours and we can put it aside in a second.

2 So you have a document cited here,

3 ETH.MESH10186745, and when I pulled that document to look
4 at what you're relying on, that was a clinical expert
5 report for the Gynecare Prolift Pelvic Floor Repair System
6 dated July 2nd, 2010; correct, what is page 45 of that?

7 A. That's what this is, yes.

8 Q. And this document doesn't actually have
9 anything to do with or support the opinions that you have
10 in this first sentence on page 17 that ends with footnote
11 28; correct?

12 A. I'm sorry, that was a typographical error.

13 Q. Okay. Did you make that typographical error
14 or did someone else?

15 A. It's hard to say because what I did was I put
16 the footnote reference after the period, and then I had an
17 assistant actually convert that to a footnote. So I can't
18 say whether I made the error when I had it typed here,
19 where you see -- in other words, I didn't do the
20 footnoting activity myself. I put the references at the
21 sentences, and then I had a document clerk convert that
22 reference to the actual footnote you see below.

23 Q. Okay.

24 A. And so at either of those two junctures, there

1 could have been a transposition error.

2 Did you check the other one?

3 Q. I did, and this is the one I couldn't -- this
4 is the one I couldn't -- that's going to be part of the
5 record.

6 MR. DAVIS: Fidelma, I think I found
7 another one somewhere. You may come to it.

8 BY MS. FITZPATRICK:

9 Q. Well, so let me clarify for the record.

10 A. Can you say what -- what it was supposed to
11 be? I don't have a pen. Can I mark it what it was
12 supposed to be?

13 Q. So I think I was understanding
14 ETH.MESH10586745 is what it should have been; is that
15 right?

16 MR. DAVIS: I've got a copy of it here.

17 MS. FITZPATRICK: That's okay. I'm
18 going to have to take a look at that, though, because --

19 BY MS. FITZPATRICK:

20 Q. Were there any other errors in this report to
21 documents that were cited in your footnotes that you are
22 aware of sitting here today?

23 A. I have been told there's at least one
24 additional one.

1 Q. Okay. Can you tell me which one that is?

2 MR. DAVIS: Go off the record? I've got
3 to go to the other room and get my copy of the report.

4 MS. FITZPATRICK: Sure.

5 (Whereupon, a recess was taken from
6 10:22 a.m. to 10:35 a.m.)

7 MR. DAVIS: Would you like for her to
8 tell you where the footnote typos are that we've seen?

9 MS. FITZPATRICK: Yes, that would be
10 great.

11 THE WITNESS: So on page 11, the
12 ETH.MESH.000 --

13 MR. DAVIS: Tell her which --

14 THE WITNESS: Oh, I'm sorry, Number 12.

15 BY MS. FITZPATRICK:

16 Q. Okay.

17 A. The second footnote that's supposed to be
18 referencing the hernia mesh 510(k) clearance letter --

19 THE REPORTER: Referencing the what?

20 THE WITNESS: Oh, I'm sorry, I had my
21 hand in front of my mouth. It's a hernia mesh 510(k)
22 clearance letter, and that Bates number is incorrect.

23 BY MS. FITZPATRICK:

24 Q. Okay. Can you give me the correct one?

1 MR. DAVIS: I will get it for you. I
2 don't have it yet.

3 BY MS. FITZPATRICK:

4 Q. Okay.

5 A. And then Footnote Number 16, my handwriting,
6 ETH.MESH should be .10178872.

7 Q. Hold on, 78872. So the first 8 should be a 7?

8 A. The first 8 should be a 7, and then the rest
9 of that Bates number is correct.

10 Q. Okay.

11 A. And go to 16, and Number 24.

12 MR. DAVIS: No.

13 THE WITNESS: No, not that one. Number
14 26, sorry. So the ETH.MESH Number 105886748 is the proper
15 number.

16 BY MS. FITZPATRICK:

17 Q. I'm sorry, 105 --

18 A. There's too many numbers. 10588.

19 Q. Uh-huh?

20 MR. DAVIS: 1058.

21 THE WITNESS: 10586748.

22 BY MS. FITZPATRICK:

23 Q. Okay. So there's 8872 should come out of the
24 middle of that; is that right?

1 A. Right, uh-huh.

2 Q. Okay.

3 A. And then the end note, end of that would be
4 1056749. So it's just two pages.

5 MR. DAVIS: And then, Fidelma, what
6 happened is the 88 -- the four digits she took out --

7 MS. FITZPATRICK: Uh-huh.

8 MR. DAVIS: -- the problem was that was
9 supposed to be two separate documents being cited there.
10 So the 8872 got tied in with the 6748. So it's actually a
11 second document there.

12 THE WITNESS: It's the
13 ETH.MESH10588872-8876.

14 MS. FITZPATRICK: Okay.

15 THE WITNESS: And there's one more.

16 MR. DAVIS: That's one you've already
17 got.

18 THE WITNESS: That's one we already got.

19 MS. FITZPATRICK: Is that it?

20 MR. DAVIS: That's all I've seen.

21 BY MS. FITZPATRICK:

22 Q. And Ms. Duncan, were those errors that you
23 found in your review of the report, or were those errors
24 your attorneys found in review of your report?

1 A. Paul pointed them out to me.

2 Q. Okay. And you don't believe that having typos
3 in your report compromises the quality of the opinions
4 that you're offering; correct?

5 A. It doesn't alter the quality of the opinions;
6 it embarrasses me that I didn't catch those. Sorry.

7 Q. Okay. Now, Ms. Duncan, let me -- you're
8 currently the president and founder of Paladin Medical;
9 correct?

10 A. Yes, ma'am.

11 Q. And you founded that company in 18 -- sorry --
12 1987?

13 A. Move to strike.

14 Q. Fair enough. We'll strike that one.

15 You founded that company in 1987; is that
16 right?

17 A. Yes.

18 Q. And is it fair to say that your company
19 specializes in regulatory and clinical strategies for
20 medical device companies?

21 A. We specialize in a number of activities, but
22 clinical compliance, regulatory development, as you see on
23 the website, I offer a number of services.

24 Q. Okay. Now, is the CV that you have provided

1 in your report, is that your most up-to-date CV?

2 A. Yes, ma'am.

3 Q. Okay. And tell me, what did you do to prepare
4 for your deposition today?

5 A. I got a good night's sleep, and I reviewed the
6 deposition of Anne Wilson, and I reviewed her markup of my
7 report and her markup of her report, and I think that's
8 pretty much it.

9 Q. Did you meet with anyone yesterday?

10 A. Yes.

11 Q. And who did you meet with?

12 A. Paul and -- and Phil here.

13 Q. And how long did you meet with them?

14 A. Probably about four hours.

15 Q. Okay. And apart from the four-hour meeting
16 that you had yesterday to prepare for the deposition, did
17 you meet with them at any other time to prepare for the
18 deposition?

19 A. I think there was a few hours on Sunday
20 afternoon.

21 Q. Sunday afternoon?

22 A. Uh-huh.

23 Q. And who did you meet with then?

24 A. Paul, Phil and then Chad Hutchinson, and

1 Stephen Myers.

2 Q. So is it fair to say you spent about six hours
3 preparing for the deposition?

4 A. I would say that's about right.

5 Q. And what I was referring to is just the
6 meetings that you had; correct?

7 A. The meetings; right.

8 Q. And in addition to those meetings, about how
9 much time did you spend on your own preparing for the
10 deposition?

11 A. Oh, probably about the same amount of time in
12 reviewing.

13 Q. So 10 to 12 hours total?

14 A. I would say more like 10, yeah.

15 Q. Okay. Now, you mentioned -- I want to make
16 sure that I have this right. You mentioned markups of
17 certain documents; correct?

18 A. Yes.

19 Q. And do you have those with you?

20 A. Yes, they're the markups of -- these are Anne
21 Wilson's, Anne Wilson's copy that she marked up, plus a
22 few pages of my own markup on those same pages, I think,
23 maybe some notes on here, and then her -- my report with
24 her markups.

1 Q. Okay. And can we go ahead and get what you
2 have there marked as -- separate that out so we have it
3 all. I think we're on number -- if I can take a look at
4 what you have there.

5 A. (Handing.)

6 Q. First is the report of Ms. Wilson; is that
7 right?

8 A. That's correct.

9 Q. And it's got a number of notes on it, and it's
10 got some tabs on it. Let's mark this as Deposition
11 Exhibit Number 4, and if you can take a look at it and
12 tell me whose handwriting is on that document?

13 (Whereupon, Exhibit 4 was marked.)

14 THE WITNESS: So it's Anne's, except
15 there's a page -- the Post-its are mine. Then this is an
16 extra page 9. This is my note.

17 BY MS. FITZPATRICK:

18 Q. So page 9 with the red handwriting on it?

19 A. Uh-huh, that's mine.

20 Q. Okay.

21 A. And page 14 is a duplicate. This is my
22 handwriting.

23 Q. Okay. That's page 14 with black handwriting?

24 A. And I wrote "ED's copy" up here.

1 Q. Okay. Great. Thank you very much.

2 MR. DAVIS: There's other handwriting on
3 that page. Which part is yours?

4 THE WITNESS: Oh, mine? I'm in the
5 margin.

6 MS. FITZPATRICK: Okay.

7 MR. DAVIS: Is all the handwriting on
8 that page your handwriting, everywhere on that page?

9 THE WITNESS: Yes, that's the way I did
10 it, so that this is Anne's markup, and then this is my
11 page with my markups (pointing).

12 BY MS. FITZPATRICK:

13 Q. Just so the record is clear, there's a page in
14 the upper left-hand corner that says "ED's copy" and has
15 got handwriting on it.

16 That's your handwriting?

17 A. That's mine.

18 Q. There's also a second page 14 that has
19 photocopy notes on it. That's Ms. Wilson's handwriting;
20 correct?

21 A. That's right. That's right, because this was
22 an exhibit from her deposition. And I believe that's the
23 only two pages that are duplicated. The rest are all
24 Anne's, just to be double-sure.

1 Also, I flagged this one because it was an
2 exhibit that, when I looked at her original report, I
3 didn't have.

4 Q. Okay. Let me -- what you're referring to
5 there is Figure 5, the report exhibit of Ms. Wilson, it
6 doesn't have a page number at the bottom.

7 So we'll mark that as Exhibit Number 4.

8 A. Okay.

9 Q. And then Exhibit Number 5 is a copy of your
10 expert report in this, or at least just the text of your
11 expert report without the --

12 A. Right.

13 Q. Okay.

14 A. And then, they're all Anne's notes.

15 Q. Okay. And the yellow flags that are on this,
16 those are your yellow flags; correct?

17 A. That's correct.

18 Q. All right?

19 A. And that last page is not a part of the
20 report.

21 Q. Okay. Thank you. So we'll mark that as
22 Exhibit 5.

23 (Whereupon, Exhibit 5 was marked.)

24

1 BY MS. FITZPATRICK:

2 Q. Then you also have in here a photocopy -- or a
3 color copy of Ethicon meshes, and it looks like everything
4 from MERSILENE from 1950 to PHYSIOMESH in 2010.

5 Did you bring that with you, as well?

6 A. Yes.

7 Q. Okay. Can you tell me why you brought that
8 with you?

9 MS. FITZGERALD: Mark that as Exhibit 6.

10 (Whereupon, Exhibit 6 was marked.)

11 THE WITNESS: It was stuck in the back
12 of the book, and I forgot it was there.

13 BY MS. FITZPATRICK:

14 Q. Okay.

15 A. It was in back.

16 Q. It just happened to be there?

17 A. Yeah. It is a document from the reference
18 list.

19 Q. Okay. Perfect. And in addition to that, you
20 have some handwritten notes in front of you.

21 Can you identify for me what those are?

22 A. They're some notes I took. The yellow paper
23 is kind of a first attempt at a timeline.

24 Q. Okay. And those are your handwritten notes?

1 A. That's right.

2 Q. Okay. So it looks like here -- is it only
3 your handwritten notes?

4 A. Yes, I write rather differently with different
5 pens.

6 Q. Okay.

7 A. So I was attempting to create a timeline as I
8 was looking at the original documents.

9 Q. Okay.

10 A. And you see I drew a line there as to where I
11 was going to stop. When I started looking at all the
12 documents, I was looking at everything, just opening them
13 up at random, and when I would find a document, I would
14 try to pin the tail on the donkey; where did it belong in
15 the time frame.

16 Q. Okay. So this is your first attempt to do
17 that?

18 A. Right.

19 Q. Okay. We'll mark this as Exhibit 7.

20 (Whereupon, Exhibit 7 was marked.)

21 BY MS. FITZPATRICK:

22 Q. And you have another handwritten --

23 A. Yes, just some notes I wanted to have handy to
24 remind myself about certain things that I found.

1 Q. Okay. And let's go ahead and mark that as
2 Deposition Exhibit Number 8.

3 (Whereupon, Exhibit 8 was marked.)

4 BY MS. FITZPATRICK:

5 Q. And what else did you bring with you?

6 A. I have a copy of the AUGS statement.

7 Q. Let's go ahead -- now, parts of this are
8 highlighted and underlined.

9 Are those your highlights and underlining?

10 A. Yes, ma'am.

11 Q. Okay. Let's go ahead and mark this as
12 Deposition Exhibit Number 9.

13 (Whereupon, Exhibit 9 was marked.)

14 BY MS. FITZPATRICK:

15 Q. Now, I think, when we started today, you said
16 you haven't done a deposition, probably, since the late
17 1980s; is that correct?

18 A. That's correct.

19 Q. And what kind of case was that?

20 A. I was deposed for the 3M breast implants.

21 Q. And were you testifying on behalf of the
22 manufacturer of the breast implants?

23 A. I was a former employee of 3M, and they -- the
24 plaintiffs had subpoenaed me.

1 Q. Okay. So that wasn't in connection with any
2 expert services that you had --

3 A. No, I was just subpoenaed as a previous
4 employee.

5 Q. Okay. And have you been deposed as an expert
6 witness in any litigation before?

7 A. No, this is my first time.

8 Q. So then, obviously, you haven't testified at
9 trial; correct?

10 A. No.

11 Q. Have you prepared any other expert reports in
12 connection with other litigation?

13 A. No.

14 Q. So this is the first time, your -- your trial
15 run at the expert?

16 A. Yes, ma'am.

17 Q. And you were familiar with pelvic mesh prior
18 to being retained by Ethicon in connection with this;
19 correct?

20 A. Somewhat familiar, yes.

21 Q. And you had worked for Proxy Biomedical;
22 correct?

23 A. Proxy Biomedical, yes.

24 Q. And you're also familiar with the

1 Boston Scientific pelvic mesh products; correct?

2 A. Yes, to some extent. Yes.

3 Q. Were you -- we're going to talk about that in
4 a minute, but were you familiar at all with any of the
5 Ethicon products, pelvic mesh products, prior to being
6 retained in this litigation?

7 A. None of the pelvic mesh, no.

8 Q. Had you worked at all, with PROLENE mesh prior
9 to being retained in this litigation?

10 A. I had not worked with it. I had referenced it
11 in 510Ks.

12 Q. And what 510Ks did you reference that in?

13 A. As I'm trying to recall, they would have been
14 hernia mesh 510(k)s and probably the Proxy Biomedical
15 510(k).

16 Q. Okay. But apart from that, you've never
17 worked with Ethicon PROLENE in connection with any kind of
18 pelvic mesh product before; correct?

19 A. No, I worked on an instrument that was a
20 design project for pelvic mesh deployment, but it was an
21 independent physician idea, and we weren't specific on any
22 particular mesh. It was just trying to develop a better
23 tool, and that's the closest I've come to anything with
24 respect to pelvic mesh.

1 Q. When was that?

2 A. Probably three years ago.

3 Q. Okay. And what physician were you working
4 with in connection with that?

5 A. I can't even recall. I was retained by the
6 development company.

7 Q. And what was your involvement with that
8 device?

9 A. The development company had asked me to help
10 them assess the regulatory strategy and the requirements
11 for testing that would be required to get the instrument
12 cleared through a 510(k).

13 Q. And can you describe to me what that
14 instrument was?

15 A. It was a minimally-invasive deployment tool,
16 and actually, the design would be confidential, so I
17 couldn't go much further than that, anyway.

18 Q. Was it used for a stress urinary incontinence
19 polypropylene sling?

20 A. It wasn't specific to that. It could
21 have used any mesh.

22 Q. Okay. Was it specific to stress urinary
23 incontinence as opposed to pelvic organ prolapse?

24 A. As I recall, it was pelvic organ prolapse.

1 Q. Okay. And do you remember whether it was
2 pelvic organ prolapse, either in the anterior compartment
3 or the posterior compartment?

4 A. No, I don't. I don't have -- I only saw
5 videotapes of the device in a cadaver study, so I couldn't
6 be very specific with it.

7 Q. Do you know if that product ever came to
8 market?

9 A. I believe it did not.

10 Q. Do you know why it didn't come to market?

11 A. I think that the atmosphere had changed.

12 Q. Concerning pelvic organ prolapse mesh devices?

13 A. The physician just decided not to pursue it.
14 That's all I was told.

15 Q. Okay. Now, are you aware that there are 37
16 different plaintiffs involved in this current case that
17 you've offered your expert opinion in?

18 A. I can read the names on the front.

19 Q. Okay.

20 A. That's my level of awareness.

21 Q. Okay. And I think that we discussed
22 earlier -- make sure I'm correct -- that you know that
23 they have a TVT retropubic device but were not aware
24 whether it was mechanical cut or laser cut prior to the

1 deposition today; correct?

2 A. I'm not aware of what they knew or did not
3 know.

4 Q. I'm asking you whether you knew?

5 A. I -- ask me the question again. I'm sorry,
6 there was too many "knews."

7 Q. And I think I asked you this earlier, but
8 prior to coming to the deposition today, you were not
9 aware that all of these women had TVT retropubic
10 mechanically-cut devices; correct?

11 A. I had not gotten into that discussion at all.
12 I didn't know anything about the plaintiffs, and it wasn't
13 an issue for me to do my job.

14 Q. Okay. And you didn't distinguish between the
15 mechanically-cut TVT-R and the laser-cut TVT-R for
16 purposes of the report that you generated today; correct?

17 A. No, I did.

18 MR. DAVIS: Wait a second. Object to
19 the form of the question.

20 THE WITNESS: Yeah, I did distinguish.

21 BY MS. FITZPATRICK:

22 Q. Okay. So you recognize that those are
23 separate products; correct?

24 A. They have the mesh in common and they have

1 different manufacturing processes.

2 Q. Okay. So they're related but separate
3 products; would that be fair?

4 A. They're related and separate products.

5 Q. Okay. And --

6 A. And again, the only reason I considered any of
7 these was because Ms. Wilson had already, in her report,
8 started talking about the laser device, so I had to
9 incorporate my review, as well.

10 Q. Okay. Fair enough. And you know that, from
11 reviewing Ms. Wilson's report, that she drew a distinction
12 between the TVT-R laser cut and the TVT-R mechanical cut;
13 correct?

14 A. I believe she did, in some places, yes.

15 Q. Okay. Now, this isn't the first time that
16 you've been hired by a medical device company; correct?

17 A. Certainly not.

18 Q. How many medical device companies have you
19 worked for before?

20 A. I tried to count them, and I went back
21 about 300, and my records were too old to pull up.

22 Q. And of those hundreds of medical device
23 companies that you've worked for, how many projects
24 involved a permanently-implantable medical device?

1 A. Let me see my CV for a second. It's hard to
2 recall. In my CV, in the "Profiles of Success" in the
3 back.

4 Q. Okay. And that would be pages 12 and 13?

5 A. Yes.

6 Q. Okay.

7 A. Of the CV, yes. So this is a list that I --
8 it essentially represents what's on my website, and it
9 may be a little more current than what's on my website,
10 but this is the list of devices for which I give notice,
11 if you will, to potential clients that I have worked on
12 these devices. The vast majority of them, I suppose, are
13 implantable.

14 Q. Okay. So if I looked at pages 12 and 13, I
15 can take a look at what your involvement with permanently-
16 implanted medical devices is; is that right?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: My involvement, it doesn't
19 describe my involvement. It describes the devices and
20 types that I've worked with.

21 BY MS. FITZPATRICK:

22 Q. Fair enough.

23 A. But it doesn't go into detail.

24 Q. Fair enough. But this will identify what

1 those devices are?

2 A. Yeah.

3 Q. Okay. How many employees does your company
4 have?

5 A. It varies, but right now, we have four.

6 Q. And how does it vary? Can you give me the low
7 to high in the last 10 years? Let's not go back all the
8 way to 1987.

9 A. I typically hold it down to about six is the
10 maximum.

11 Q. And it's fair to say that the vast majority,
12 if not all of the work that you do and the income you
13 derive comes from work with medical device companies;
14 correct?

15 A. I work with some universities.

16 Q. And how much of your work is involved with
17 universities, just a general ballpark percentage?

18 A. Probably university development projects or
19 university consulting would probably be 15, 20 percent,
20 maybe.

21 Q. And so the remaining 80 to 85 percent of your
22 business involves work with medical device companies;
23 correct?

24 A. Let me clarify, too, that sometimes the

1 companies aren't companies yet.

2 Q. Okay.

3 A. They're -- they may be physicians or inventors
4 that haven't formed a company.

5 Q. Okay.

6 A. And that might be another 5 percent.

7 Q. Okay. And when you're working with these
8 physicians who are not quite companies yet, that
9 involves the -- that involves medical devices; correct?

10 A. Yes.

11 Q. And in fact, you have on your website that
12 your company is dedicated to the service of medical device
13 manufacturers.

14 That would be accurate; isn't it?

15 A. Yes, and want-to-be manufacturers.

16 Q. And want-to-be -- okay, I like that phrase.
17 Want-to-be manufacturers and actual manufacturers; is that
18 right?

19 A. That's correct.

20 Q. And in fact, your company's business really
21 depends on current future business from want-to-be
22 manufacturers and actual manufacturers; correct?

23 A. That's correct.

24 Q. That's required for your continued financial

1 success.

2 But what percentage of your annual revenue
3 comes from your work with medical device companies or
4 want-to-be medical device companies?

5 A. I guess the best way to say it is I receive no
6 royalties from patents or anything else, so this would
7 be -- this is the way I earn a living, is by consulting.

8 Q. Okay. And that living that you earn or those
9 revenues that you bring in, are about 80 to 85 percent of
10 those attributable to your work with actual medical device
11 companies or want-to-be medical device companies?

12 A. That's correct.

13 Q. And you don't make a distinction between how
14 much you charge a medical device manufacturer and how much
15 you charge a university?

16 A. I probably charge the universities too little
17 for my effort.

18 Q. Okay. Is there a difference in what you're
19 charging universities versus what you charge the medical
20 device manufacturers?

21 A. Well, certainly. In some aspects of my work,
22 I would say that I offer the services in anticipation
23 of their grant success, so I may consult with them before
24 they even have grant money.

1 Q. Uh-huh.

2 A. And sometimes it's a student's work, and
3 sometimes it's training, I'll go to universities and give
4 training so that, in those cases, they'll give me an
5 honorarium.

6 THE REPORTER: They'll give you a what?

7 THE WITNESS: Honorarium, sorry. And it
8 typically covers just a portion of the expenses, so it
9 varies, you know, little -- it's not a significant way to
10 make a living. It varies. Sometimes it's good work in
11 terms of ongoing, and sometimes it's sporadic.

12 BY MS. FITZPATRICK:

13 Q. And what percentage of your personal income is
14 derived from Paladin Medical Incorporated?

15 A. Except from what I inherited from my mother, I
16 would say 100 percent.

17 Q. So do you advertise your services to medical
18 device companies?

19 A. I have taken advertisements in different
20 magazines, and I certainly have a website and a corporate
21 Facebook page, but the majority of the time beyond that, I
22 don't advertise.

23 Q. Okay. And how did Ethicon, if you know, come
24 to find you to retain you as an expert in this litigation?

1 A. Through I guess one or more associates. I
2 never really inquired.

3 Q. And who first contacted you from Ethicon?

4 A. Well, actually, it was from Butler & Snow,
5 Stephen Myers contacted me first.

6 Q. Okay. So you were first contacted by a law
7 firm that represented Ethicon; is that right?

8 A. Oh, yes. I didn't solicit the work.

9 Q. Okay. And when did Mr. Myers contact you?

10 A. I'm not exactly sure of the date, but I
11 believe it was approximately July 15th.

12 Q. So mid-July of this year.

13 And you've been paid for your work in this
14 case; is that right?

15 A. So far.

16 Q. Okay. And is Butler Snow paying those
17 expenses and those fees for you?

18 A. I send the invoices to them and they send them
19 on to J&J.

20 Q. Okay. And how much money have you been paid
21 for your work in this case?

22 A. I'm -- I'm going to recall. I think it's
23 around \$59,000. I haven't looked at it beyond that.

24 Q. And is that payable to you directly or is that

1 payable to your company?

2 A. No, it's to the corporation, and some of that
3 includes some travel expense.

4 Q. Okay. And how much do you charge per hour for
5 your expert services?

6 A. I have to look what I am charging here. \$250
7 per hour for time spent not involving travel, and then
8 \$325 per hour for time spent that includes travel or
9 deposition or trial testimony.

10 Q. And how does that compare to the amount of
11 money that you charge medical device manufacturers who
12 come and just hire your company for non-expert litigation?

13 A. It's in the same range, but it is a bit higher
14 for the deposition and trial testimony than average, but
15 it's within the same range.

16 Q. Now, what is LifeScience Alley?

17 THE REPORTER: What?

18 THE WITNESS: LifeScience, one word,
19 Alley. It is an organization here in the Twin Cities. I
20 believe it's a non-profit, and it has been characterized
21 as a Chamber of Commerce for medical technology.

22 BY MS. FITZPATRICK:

23 Q. And your business is a member of that
24 organization; is that right?

1 A. I believe, in this case right now, I'm an
2 individual member. I can't recall which, whether it's
3 corporate level or individual.

4 Q. Okay. And is American Medical Systems also
5 a member of that organization, to your knowledge?

6 A. I couldn't tell you. I don't -- I haven't
7 kept up with who is or isn't.

8 Q. Do you know whether Boston Scientific
9 Corporation is a member of that?

10 A. I couldn't tell you.

11 Q. Coloplast Corporation; do you know whether
12 they're a member?

13 A. They may or may not be. I don't know.

14 Q. Do you know whether Johnson & Johnson or
15 Ethicon is a member of that organization?

16 A. I would tend to doubt it. We're sort of a
17 local organization.

18 Q. And you've actually done -- actually,
19 LifeScience Alley is a successor to a different
20 organization called Medical Alley; correct?

21 A. It's a successor, yes, ma'am.

22 Q. Okay. And you've done a number of
23 presentations at Medical Alley conferences; haven't you?

24 A. And LifeScience Alley.

1 Q. And you know that medical device companies,
2 including mesh manufacturers, attend these conferences;
3 right?

4 A. I'm not -- typically, I'm not aware of who's
5 in the audience when I give a presentation. I couldn't
6 tell you who's there.

7 Q. Do you recall ever giving a presentation
8 alongside an employee for American Medical Systems?

9 A. I may have. Again, when we get into the
10 LifeScience Alley training sessions, we tend to leave our
11 company badges at the door.

12 Q. So you don't remember if you've ever given a
13 presentation on anything to do with mesh or pelvic mesh at
14 LifeScience Alley or Medical Alley conference?

15 A. I'd have to check my CV. I can't recall off
16 the top of my head.

17 Q. Now, we talked a little bit earlier about your
18 involvement with Proxy Biomedical.

19 Are you still the United States agent for
20 Proxy Biomedical?

21 A. Yes, I am. They're a U.S. agent.

22 Q. Okay. And what work do you do specifically
23 for Proxy?

24 A. I had filed some of their 510(k) submissions,

1 and I acted as the liaison when FDA issued the 522 order
2 for their particular 510(k), and as U.S. agent, I'm
3 notified when FDA does an inspection, but I'm typically
4 not involved in their inspections. I don't have to travel
5 there.

6 Q. You said you filed 510(k) submissions. What
7 products made by Proxy have you filed 510(k) submissions
8 for?

9 A. I'd actually have to refresh my memory, but
10 they've been mesh products with a rather general
11 indication for use.

12 Q. Okay. And does the Polyform mesh ring a bell
13 with you?

14 A. That's one of them, yes.

15 Q. How about the Polyform Lite mesh; does that
16 ring a bell with you?

17 A. I can't recall off the top of my head, but it
18 sounds familiar. I'm not sure. Some of their people also
19 have filed 510Ks.

20 Q. Okay. And when you're talking about the 522
21 orders, can you tell me specifically what product you're
22 referring to there?

23 A. I can't remember the 510(k) number. I'd have
24 to look that up for you.

1 Q. Would it be for the Polyform mesh?

2 A. As I recall, Polyform changed the 510(k)
3 indication for use.

4 Q. Okay.

5 A. So that's what we did; we modified the 510(k)
6 indication for use page in order to respond to the 522.
7 That much I can recall.

8 Q. Okay.

9 A. I don't recall the number.

10 Q. And you'll recall -- or am I correct that the
11 original 510(k) indication for use with the Polyform
12 included a vaginal usage for the product?

13 A. I believe at the time we filed that we were
14 trying to be as broad in our indication for use as we
15 could, and that's what was modified by the 522 order. We
16 took that out.

17 Q. Okay. And what we're talking about here when
18 we're talking about meshes, we're talking about,
19 basically, sheets of surgical mesh or patches?

20 A. They were always flat products.

21 THE REPORTER: They were what?

22 THE WITNESS: Flat.

23 BY MS. FITZPATRICK:

24 Q. And have you been involved in any of the

1 510(k) submissions for Boston Scientific where they used
2 the Polyform mesh and made it into pelvic organ prolapse
3 or stress urinary incontinence devices?

4 A. It's been many years, so I'm a little bit
5 vague. I did not refresh my memory on that. But as I
6 recall, after one of the earliest 510(k)s, I assisted in
7 getting a separate 510(k), and I can't recall if it was
8 in -- I don't recall if Boston Scientific had their name
9 on the 510(k) or if we were making it for their use, but
10 somehow they were involved, and that's all I can recall.
11 I could get more information for you if you need it. I
12 just don't recall.

13 Q. Well, are you aware that Proxy Biomedical
14 makes the Polyform mesh for use by Boston Scientific in
15 stress urinary incontinence products?

16 A. I -- I was aware of that. I don't know if
17 they continue to do that. After I got the 522 order
18 satisfied, I haven't talked to them about it since.

19 Q. Okay. And when was that?

20 A. I can't recall.

21 Q. Give me a ballpark. Within the last year,
22 three years, five years?

23 A. It would have been somewhere, I think, after
24 2012 and -- 2012 to 2013, in that time frame. When FDA

1 had called the 522 order, they held a meeting with
2 manufacturers, and I attended that meeting so I could help
3 Proxy understand what they needed to do.

4 Q. Okay. And have you been involved in any of
5 the 522 studies for Boston Scientific for products that
6 use the Polyform mesh?

7 A. No, after I assisted Proxy with changing the
8 510(k) indication for use statement, I was no longer
9 involved in those meetings, and I was not involved in any
10 of the -- I listened in on some of the early planning for
11 the registries, and Proxy made the decision to change that
12 indication for use statement. I did that filing with
13 their quality assurance person, and then that was the end
14 of the responsibility for that product.

15 Q. Okay. Are you aware whether Proxy Biomedical
16 continues to sell the Polyform mesh for use in pelvic
17 organ prolapse or stress urinary incontinence devices?

18 A. Proxy does not sell directly, to my knowledge.
19 Let me clarify that.

20 After the 522 order and the change to the
21 indication for use, their sales were limited to that
22 indication for use. So I don't have any involvement
23 with any other activities they may have with selling
24 their meshes as a component. I don't get involved in

1 that aspect. I only filed their submissions with
2 them.

3 Q. Okay. So let me make sure that I'm
4 understanding this.

5 Polyform mesh is made by Proxy; correct?

6 A. Yes.

7 Q. And that Polyform mesh can be sold directly to
8 physicians for use as a surgical mesh; correct?

9 A. I believe they have a limited distribution.

10 Q. Okay. And at one point, Proxy attempted to
11 include a vaginal or pelvic use as an indication for use
12 of its Polyform mesh; correct?

13 A. It's not stated correctly. I have to correct
14 you on that.

15 Q. Sure. Please do.

16 A. You said "at one time." The original 510(k)
17 included the vaginal indication.

18 Q. Uh-huh.

19 A. And I am not sure it said "vaginal." I can't
20 recall the exact wording. I think it was -- I know it was
21 reinforcement, and it may have been urological. I can't
22 remember exact words. So at any rate, when we had to
23 modify the indication for use --

24 Q. Okay.

1 A. -- we had to refi -- we had to file like a
2 special 510(k) to change that indication for use.

3 Q. Okay.

4 A. And after they did that, then I haven't had
5 any more activity with them.

6 Q. Okay. Let me make sure that I've got the
7 timeline right here.

8 Polyform mesh and Polyform Lite originally had
9 an indication for the pelvic use -- I'll call it pelvic
10 use.

11 A. Something, yes. That's good.

12 Q. And then the FDA issued a 522 letter
13 concerning the use of the Polyform or Polyform Lite in the
14 pelvic cavity; correct?

15 A. Not specifically. They issued the 522 order
16 for all companies. It wasn't specific to Polyform, but
17 they were included in that order.

18 Q. Okay. So Polyform was required to -- in order
19 to continue to sell Polyform for pelvic use --

20 A. Yes.

21 Q. -- Proxy was going to be required to abide by
22 the materials of the 522 letter; correct?

23 A. FDA originally gave companies an opt-in or
24 opt-out.

1 Q. Okay. And instead of doing the 522 studies
2 for pelvic use --

3 A. For their product, under their 510(k).

4 Q. Under their 510 -- I'm just talking about --
5 again, talking about the sheet, the surgical mesh.

6 A. The flat sheet.

7 Q. Instead of complying with the 522 for pelvic
8 use, Proxy changed its indications for use to abdominal
9 use only; is that right?

10 A. We changed the indication for use, and I can't
11 say abdominal only. That's a little more specific than
12 I --

13 Q. Okay. To remove the pelvic use; is that
14 correct?

15 A. That's correct. And my understanding was
16 their 510(k) and their products, as they were selling them
17 directly, that was then consistent with what their meshes
18 were actually used for because they weren't really
19 promoting or using them in pelvic because they were flat
20 sheets, and other products were more direct to pelvic
21 applications.

22 Q. Okay. So with that change, the Polyform was
23 then marketed as surgical mesh without a pelvic
24 application; is that right?

1 A. Again, I have to now limit this because I
2 can only say that I helped get the 510(k) indication for
3 use changed, and at that point, they were no longer under
4 the 522 order for that product, and I have no idea what
5 they do or don't do with any of the other companies. I
6 don't -- I'm not involved in that aspect.

7 Q. Okay. So that was going to be my next
8 question, but maybe you've answered this already.

9 After Proxy removed the pelvic use, do you
10 know whether Proxy continued to sell that Polyform to
11 Boston Scientific for use in pelvic organ prolapse or
12 stress urinary incontinence devices?

13 A. No, I was compartmented is the best way to say it.
14 I've worked only for their direct sales of 510(k)s.

15 Q. Okay. So your experience deals with the sheet
16 surgical mesh; it does not deal with the actual kits and
17 products made by Boston Scientific with that --

18 A. That's correct.

19 Q. -- Proxy mesh?

20 A. That's correct.

21 MR. DAVIS: Let me just stop you for a
22 second.

23 THE WITNESS: Yeah.

24 MR. DAVIS: And make sure she gets her

1 full question out --

2 THE WITNESS: Okay.

3 MR. DAVIS: -- before you start
4 answering. It would be better for the court reporter.

5 THE WITNESS: Oh, I'm sorry. Thank you.

6 BY MS. FITZPATRICK:

7 Q. And in connection with your work for Proxy,
8 you were familiar with the material safety data sheet for
9 Marlex polypropylene used by Proxy in both the Polyform
10 mesh and the Polyform Lite; correct?

11 A. Ma'am, I'm getting exceedingly uncomfortable
12 for you going further with the Proxy activities. First
13 off, they were confidential with my client. I've told you
14 things that are on public record, but I can't go any
15 further down the Proxy line. I don't believe it's within
16 the scope of my testimony, and I really have to tell you,
17 you're beginning to get into some confidential activities,
18 because the contents of submissions are confidential, and
19 if you want to go down that line, you're going to have to
20 get back to the questions that are pertinent.

21 If you've got questions that are -- like this
22 that are pertinent to what I've done, I'm happy to answer
23 them, but when you start to cross into Proxy's
24 confidential business, I'm not at liberty to continue to

1 answer. I've answered everything in the public domain.

2 Q. Okay. And you understand that the material
3 safety data sheet for the Marlex polypropylene used by
4 Proxy and Boston Scientific as SUI and POP products is
5 public information; correct?

6 A. Yes, I guess the MSDS sheet is public
7 information.

8 Q. And you know that's been the subject of
9 litigation with Boston Scientific for its pelvic organ
10 prolapse --

11 A. Ma'am, I did not know that, and I --

12 THE REPORTER: Pardon? You're talking
13 over each other.

14 MR. DAVIS: Try to wait a minute before
15 you start answering.

16 THE WITNESS: Okay.

17 BY MS. FITZPATRICK:

18 Q. And you know that MSDS sheet for the Marlex
19 polypropylene has been the subject of litigation with
20 Boston Scientific for its pelvic organ prolapse and SUI
21 devices; correct?

22 A. No, I did not know that.

23 Q. And do you know that that has -- okay.

24 Are you -- were you aware that Polyform is

1 made with the Marlex HGX-030 polypropylene?

2 A. I'm, again, going to tell you that I can't
3 answer anything further about Proxy. That is confidential
4 information. I'm going to stop you right here.

5 Q. I'm sorry, what is confidential about the
6 question that I just asked you so I can, maybe, skin this
7 cat a different way?

8 A. Because you're getting into information that I
9 know or may not know based on my work with that client,
10 which is still under confidentiality, and I refuse to
11 answer any further questions about Proxy business that is
12 confidential. It is outside the scope of my work in this
13 case.

14 Q. So you're not relying on any of the work that
15 you've done with Proxy in connection with surgical mesh or
16 polypropylene mesh as part of your experiences underlying
17 your report in this case; is that right?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: I disagree with the way
20 you've characterized that statement.

21 BY MS. FITZPATRICK:

22 Q. Okay.

23 A. What I can tell you is my background with mesh
24 materials of a wide variety are incorporated into my

1 experience that I brought to this project. But when you
2 ask me specific questions that are germane only to the
3 confidential work I do with Proxy, I have to stop you
4 right there because of my confidentiality agreement with
5 Proxy, and I think that should be very clear.

6 MR. DAVIS: In a minute, let's take a
7 break, but if you can finish this.

8 BY MS. FITZPATRICK:

9 Q. Okay. I mean, it's as simple as this.

10 If you're relying on that experience for what
11 you've done for Ethicon, I get to ask you about that
12 experience, and I'm not trying to get into --

13 A. And that's fine, I agree with that.

14 MR. DAVIS: Let me object that, you
15 know, for the record.

16 MS. FITZPATRICK: I didn't finish the
17 question yet. I didn't get it out.

18 MR. DAVIS: No, you made a statement
19 that if she's relying on past experience, you get to
20 ask her all the questions about it. No, she doesn't --
21 she's not required to violate confidentiality obligations.

22 MS. FITZPATRICK: You can't have
23 it both ways. You can't say she's an expert in
24 polypropylene mesh but you can't ask her about how she

1 gained that expertise and what she did. You just can't
2 have it both ways. So it's one or the other. And I'll
3 live with what that is, but you got to tell me what it is.

4 MR. DAVIS: She's not here for materials
5 expertise in this case.

6 MR. WALLACE: Here's the other thing.

7 MR. DAVIS: She's here as an expert in
8 this case for polypropylene mesh.

9 MR. WALLACE: She's being asked
10 nonconfidential questions, and perhaps you can take her
11 out in the hall and remind her of that, because you guys
12 know as well as we do that the questions that have been
13 asked are nonconfidential, so I'd rather not have to call
14 the Judge.

15 MR. DAVIS: We can go off the record.

16 THE WITNESS: Can I --

17 MR. COMBS: Stop, we're going to go out
18 and talk. I don't agree with any of the statements you've
19 made about that, but we'll talk for a second.

20 MS. FITZPATRICK: That's not too
21 shocking. We've rarely agreed, but that's all right. We
22 usually find a solution.

23 MR. COMBS: -- we'll get someone on the
24 phone to work through this. That's fine with us.

1 (Whereupon, a recess was taken from
2 11:24 a.m. to 11:36 a.m.)

3 MR. DAVIS: Let me see if I can try to
4 take a stab at clearing something up on the question.

5 MS. FITZPATRICK: Awesome.

6 MR. DAVIS: I can represent to you that
7 she is not going to be relying on work for Proxy for -- at
8 some specific reference that she intends to testify about.
9 She -- her only reliance on Proxy is simply part of her
10 general background and experience of understanding and
11 working with all the various standards and regulations,
12 but she intends to offer no testimony at all about --
13 about Proxy or any of her specific work with Proxy.

14 MS. FITZPATRICK: Okay. I --

15 MR. DAVIS: And let me give you one more
16 example.

17 Your question, as I understand it, that
18 started all this was a question, "Are you aware of such
19 and such about Proxy?" And I can't remember what the
20 detail was, but in Ms. Duncan's mind, whether or not she
21 is aware of what it was you're asking her about, that, in
22 and of itself, is confidential, whether or not she's aware
23 of it. And so, you know, that's what -- and again, she --
24 you know, she is not going to be relying on anything

1 specific about her work with Proxy, you know, in her
2 testimony. I can represent that.

3 MS. FITZPATRICK: Why don't we do this?
4 I don't want to belabor this point. I don't want to waste
5 our time having a fight about this. Let me ask my
6 questions. If she won't answer because of
7 confidentiality, let's just put it on the record.

8 MR. DAVIS: That's fair.

9 MS. FITZGERALD: When we get to the end
10 of it, let me figure out whether I need to deal with it
11 further or not.

12 MR. DAVIS: Fair enough.

13 MS. FITZPATRICK: But let's just deal
14 with that way and we'll get through.

15 MR. DAVIS: That's a good solution.

16 BY MS. FITZPATRICK:

17 Q. Ms. Duncan, in your work with surgical meshes,
18 you have worked with material safety data sheets; correct?

19 A. That's correct.

20 Q. And in your work with surgical meshes, you
21 have looked at the material safety data sheets as
22 important pieces of information and understanding the
23 material that the surgical mesh is made of; correct?

24 A. It's a part of it, yes.

1 Q. But it's an important part of it; correct?

2 A. They are of limited value these days. The
3 MSDS sheets have limited value.

4 Q. Okay. But you'll agree with me that it
5 certainly is something that contains information relative
6 to the material that's being used in the medical device;
7 correct?

8 A. It's a contributing factor, yes.

9 Q. Okay. And you are aware that the MSDS sheet
10 for Marlex HGX-090 contains a medical application caution;
11 correct?

12 A. I am not at liberty to say.

13 Q. Do you believe that a medical -- well, and are
14 you citing confidentiality for that?

15 A. Yes.

16 Q. Okay. And are you aware that the MSDS
17 sheet -- let me do this separate and apart from -- let's
18 mark this as the next exhibit.

19 (Whereupon, Exhibit 10 was marked.)

20 BY MS. FITZPATRICK:

21 Q. I've put in front of you a material safety
22 data sheet from Phillips Sumika concerning Marlex
23 polypropylene, all grades; correct?

24 A. Yes, that's what it says.

1 Q. And this material safety data sheet, on page 1
2 at the bottom, has a medical application caution on it;
3 correct?

4 A. It does.

5 Q. Okay. And it says to not -- it says, "Do not
6 use this Chevron Phillips Chemical Company LP material in
7 medical applications involving permanent implantation in
8 the human body or permanent contact with internal body
9 fluids or tissues"; correct?

10 A. This is what the document says.

11 Q. Okay. And you will agree with me that
12 material safety data sheets concerning whatever brands of
13 polypropylene are being used by a medical device
14 manufacturer are something that should be considered and
15 looked at when doing a hazard and risk assessment;
16 correct?

17 MR. DAVIS: Objection to form.

18 THE WITNESS: That question was
19 convoluted. I -- I'm going to have to have you repeat it.

20 (Discussion off the record.)

21 BY MS. FITZPATRICK:

22 Q. You'll agree with me that the material safety
23 data sheets concerning the polypropylene being used in the
24 medical device are something that should be considered by

1 the manufacturer when doing a hazard assessment and risk
2 assessment; correct?

3 A. It's a portion of it.

4 Q. And --

5 A. As I said, they're of limited value these
6 days.

7 Q. And material safety data sheets can provide
8 information to a manufacturer on how that particular
9 material may interact with the human body; correct?

10 A. It has limited information for that.

11 Q. But relevant information, albeit you consider
12 it limited; right?

13 A. We certainly review it, but it -- it's limited
14 because of its focus to occupational exposure.

15 Q. Well, certainly something that says "Don't use
16 it for permanent implantation in the human body" has
17 nothing to do with an occupational exposure; correct?

18 A. Well, you've pointed that sentence out
19 previously. That's -- that would be something you would
20 want to pay attention to, yes.

21 Q. Okay. And my question is to you, that
22 certainly doesn't -- that's not involved with an
23 occupational exposure; correct?

24 A. It's a caution, but what I know is, not

1 uncommon, is that companies can put statements like this
2 in documents like this and then make separate deals with
3 different companies to allow them to go on and use the
4 material in ways that they have stated in the material
5 safety data sheet that they would prefer that they not
6 be used for, and it's called product licensing, and
7 that happens from time to time.

8 So just because I see something like this on a
9 material safety data sheet does not mean that I
10 immediately believe that it is never to be used in a
11 medical device. It may or may not be used in a medical
12 device, despite this caution.

13 Q. Do you know whether there's any -- I think you
14 called it private licensing -- done between Phillips
15 Sumika for their Marlex polypropylene and any medical
16 device manufacturer who makes polypropylene --

17 A. I have no specific knowledge in that regard.

18 Q. -- polypropylene surgical mesh?

19 A. I'm sorry, when you drop your voice, I think
20 you're finished.

21 Q. Okay.

22 A. So speak to my face and I won't do that
23 again.

24 Q. Okay. So don't complain later if I'm in your

1 face.

2 A. All right. Fair enough.

3 Okay. So no, I do not -- I have no knowledge
4 of any special agreements that Marlex might have that
5 would be proprietary information.

6 Q. Okay. And are you aware that Polyform mesh is
7 made from Marlex polypropylene?

8 A. I'm not at liberty to answer.

9 Q. Are you aware that Polyform Lite mesh is made
10 from Marlex polypropylene?

11 MR. DAVIS: Slow down.

12 THE WITNESS: I'm not at liberty to
13 answer.

14 THE REPORTER: Can you repeat the
15 question?

16 MR. DAVIS: I'm sorry, I was telling her
17 to slow down, so I think she may have missed that
18 question.

19 BY MS. FITZPATRICK:

20 Q. Are you aware that Polyform Lite is made with
21 Marlex polypropylene?

22 A. I'm not at liberty to answer.

23 Q. Okay. And do you know what the difference
24 between Polyform and Polyform Lite is?

1 A. I'm not at liberty to answer.

2 Q. Are you aware of any reason why surgical mesh
3 manufacturers have gone to a lighter-weight, larger-pore
4 surgical mesh?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: I'm not at liberty to
7 answer.

8 BY MS. FITZPATRICK:

9 Q. Have you seen any Ethicon documents where
10 Ethicon considered making mesh that was lighter-weight or
11 larger-pore than the original PROLENE mesh that is used in
12 TVT-R?

13 A. Yes, with respect to the work I have done, I
14 saw some documents that discussed different mesh weights,
15 yes, ma'am.

16 Q. And that is something that Ethicon considered,
17 you'll agree with me, in connection with reducing the risk
18 of its polypropylene mesh products, correct?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I disagree with that
21 characterization. If I could have you restate, perhaps,
22 the question.

23 BY MS. FITZPATRICK:

24 Q. Sure. Why did Ethicon consider going to a

1 lighter-weight mesh than the original PROLENE mesh that's
2 used in the TVT-R mechanical cut, to your knowledge?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: I can't speak to why they
5 were considering it. I can tell you that I saw documents
6 where they were considering it.

7 BY MS. FITZPATRICK:

8 Q. And in reviewing the documents that you've
9 looked at for this case, you didn't see any reason given
10 by Ethicon for why it was considering moving to a
11 lighter-weight mesh than what was the PROLENE mesh used in
12 the TVT-R mechanical cut?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: Yes, considering the issue
15 that you're talking about, I have to repeat. You've
16 altered the context. The context of the discussion of the
17 lighter-weight mesh was not with respect to TVT. As I
18 recall, I believe that what I recall reading had to do
19 with use in other pelvic applications. I don't recall
20 specific -- I do know that there were testing -- there was
21 testing done in animals on different variations of mesh.
22 I don't specifically recall the reason they did those
23 studies.

24

1 BY MS. FITZPATRICK:

2 Q. Okay. So let me make sure we're on the same
3 page here.

4 The TVT-R mechanical cut is made with a
5 PROLENE mesh; correct?

6 A. Yes, ma'am.

7 Q. And that is the same PROLENE mesh that has
8 been historically going back to -- get your document
9 here -- can I grab this from you, on the bottom?

10 A. Sorry.

11 Q. -- going back to 1975 been used as a surgical
12 mesh; correct?

13 A. Yes, ma'am.

14 Q. And 1975 through about the late 1990s, PROLENE
15 mesh was generally used in a hernia application; correct?

16 A. Let me --

17 Q. Let me show you Exhibit 6 if that helps you.

18 A. PROLENE -- say your question again.

19 Q. From 1975 to the late 1990s, PROLENE mesh was
20 generally used in hernia applications; correct?

21 Do you know that?

22 A. Yeah, I would agree with that.

23 Q. Okay. And in the late 1990s, the PROLENE mesh
24 was incorporated into the TVT-R mechanical cut; correct?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: You said "incorporated
3 into"?

4 BY MS. FITZPATRICK:

5 Q. It was used in.

6 A. Okay. I believe the PROLENE mesh was used in
7 the TVT mesh as it had been developed, and I can't recall
8 the exact year, but it was the -- I would call it the
9 standard mesh, yes.

10 Q. And what we were referring to, and we'll
11 talk about in a little bit, was you are aware that Ethicon
12 was contemplating a lighter-weight mesh than the PROLENE
13 mesh for incorporation into its pelvic organ prolapse
14 repair products; correct?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: I was not certain as to
17 which applications they had in mind, but I do recall
18 reviewing documents where they were evaluating alternative
19 mesh, types and styles and composition.

20 BY MS. FITZPATRICK:

21 Q. Do you recall any documents where Ethicon was
22 considering moving from the PROLENE mesh to a
23 lighter-weight mesh for the TVT-R mechanical-cut product?

24 Did you see anything like that?

1 A. I can't recall if it was specific to the TVT
2 mesh or not.

3 Q. Okay.

4 A. I do recall the different mesh work but not
5 whether it was specific to mechanical.

6 Q. Okay. And have you ever taught a course
7 related to the design of medical devices?

8 A. Yes.

9 Q. And what courses are those?

10 A. I'd have to refresh my memory on my CV here.
11 Okay. I have one, "Design Control for Professors,"
12 University of Kentucky in 2009.

13 Q. Is that a semester-long course?

14 A. No, ma'am.

15 Q. How long did that course --

16 A. I believe that was a day.

17 The "Navigating Standards and Regulations for
18 Medical Textiles," at the IFAI Medical Textile Symposium
19 in 2006 included some aspects of design because we were
20 discussing standards and regulations.

21 Q. And that course, how long was that course?

22 A. That was an hour. It was an hour
23 presentation.

24 I can tell you that the specific training I've

1 done with respect to clients where I've done training at a
2 client location for specific tasks I have not typically
3 included that. It was more of a commissioned work
4 specific to a client, so those may not be listed here, so
5 when you're asking me about day-long programs --

6 Q. Let me make a distinction for you.

7 Have you ever taught a course a full semester
8 long or a course at a university about the design of
9 medical devices?

10 A. No, I typically give more one to two-hour
11 programs. Just last weekend, I gave one at the University
12 of Kentucky.

13 Q. Okay. And you don't have a Ph.D.; correct?

14 A. No, I do not.

15 Q. But on your CV, it says that you've completed
16 coursework for your Ph.D.?

17 A. Yes.

18 Q. Is that something you're continuing to work
19 on?

20 A. No.

21 Q. What field were you working on a Ph.D. in?

22 A. Biomedical engineering.

23 Q. Okay. And when did you stop working on that
24 Ph.D.?

1 A. I believe it was '82 when I went to Salt Lake.

2 Q. And why did you stop working on that?

3 A. I was asked to join the company in Salt Lake
4 City building the artificial heart program.

5 Q. Okay. And you haven't completed that
6 coursework in the last, I don't know, 30 years?

7 A. I decided not to continue that.

8 Q. And are you a medical -- a biomedical
9 engineer?

10 A. My degrees are in mechanical with minors in
11 biomedical.

12 Q. And do you hold yourself out as an expert in
13 biomedical engineering?

14 A. I do not consider myself a professional
15 engineer in the context of the PE, professional
16 engineering license.

17 Q. And you're not a polymer scientist; are you?

18 A. No, ma'am.

19 Q. And you're not a medical doctor, I think we
20 established before; correct?

21 A. That's correct.

22 Q. And because you're not a medical doctor,
23 you're not able to give expert opinions on the
24 medical/clinical risk-benefit of the TVT-R mechanical cut

1 to patients; are you?

2 A. Ma'am, I can read and discern the
3 documentation, but I wouldn't give an expert opinion about
4 it.

5 Q. Okay. And of the publications listed on your
6 CV, how many of those have been peer-reviewed?

7 A. All of them on page 3.

8 Q. Okay.

9 A. And the one on -- at the top of page 4.

10 Q. Page 3, the articles and book chapters, all of
11 those on page 3 are peer-reviewed; is that right?

12 A. Yes, and then the abstract that went to the
13 ASAIO in 1998 was peer-reviewed.

14 Q. Okay. And of those maybe 10 to 15
15 publications, how many of those involved surgical mesh?

16 A. Well, we have the one development and
17 regulation of medical technology have been -- that was
18 a general one about all meshes, not specific to
19 urological meshes because it was directed to companies
20 in the textile industry, and I believe that's no more.

21 Q. Okay.

22 A. Oh, I'm sorry, the chapter, "Regulatory
23 Environment for Biotextiles," of course that would be --
24 included general textiles.

1 Q. Okay. Chapter 7, that's at the beginning?

2 A. Yes.

3 Q. Okay. Now, you've never published

4 specifically on PROLENE mesh; have you?

5 A. No, not specific to PROLENE.

6 Q. Have you ever published on polypropylene in

7 general?

8 A. No, ma'am.

9 Q. Have you ever published -- before your work

10 here, you've never provided Ethicon with any expert

11 services related to PROLENE mesh; have you?

12 A. That's correct.

13 Q. And the only work that you had done was for

14 another company that uses a different polypropylene in

15 their surgical meshes; correct?

16 A. I am not at liberty to describe the polymers

17 that they used, but it was a different company.

18 Q. Okay. Is the Ethicon TVT-R mechanical cut

19 made with Marlex polypropylene made by Phillips Sumika?

20 A. I'm sorry, say again.

21 Q. Is the Ethicon TVT-R mechanical cut made with

22 Marlex polypropylene made by Phillips Sumika?

23 A. I'm not recalling.

24 Q. Do you know what polypropylene is used by

1 Ethicon in --

2 A. I would have to check my references. I can't
3 remember that exactly.

4 Q. And you would agree with me that's something
5 that's important to know when considering the design of a
6 medical device; correct?

7 A. Well, when I was considering the design of the
8 medical device, this is -- let me explain.

9 When I'm looking at a design and involved in
10 the design and development, I would certainly want to know
11 what the polymer was. When I was reviewing these
12 documents, I recall seeing that they have MSDS sheets, but
13 I can't tell you at this moment, from recall, the exact
14 content of those MSDS sheets.

15 Q. Okay. So you don't know, sitting here today,
16 whether the TVT-R mechanical cut is made with Marlex
17 polypropylene or not?

18 A. I cannot recall. As I said, I'd have to look
19 at my references.

20 Q. Okay. You've never actually published
21 anything on the TVT product; correct?

22 A. No, ma'am.

23 Q. And you haven't published anything on the
24 differences between mechanical-cut and laser-cut surgical

1 meshes; correct?

2 A. No, ma'am.

3 Q. Now, based on your work here, do you
4 understand that there are clinical differences between the
5 TVT-R and the TVT-O devices?

6 A. Clinical surgical approach.

7 Q. And you understand that they're implanted in a
8 different manner; correct?

9 A. Yes, ma'am.

10 Q. And you understand that they're implanted into
11 a different anatomical location; correct?

12 A. Yes, ma'am.

13 Q. And do you also understand that there's a
14 difference between the mechanically-cut mesh and the
15 laser-cut mesh made by Ethicon?

16 A. Ask me the question again, please.

17 Q. Sure. Do you also understand that there's a
18 difference between the mechanically-cut mesh and the
19 laser-cut mesh made by Ethicon?

20 A. There are differences, but there are also
21 similarities.

22 Q. Okay. And do you understand that Ethicon
23 developed the laser-cut mesh to specifically deal with the
24 problems that physicians were seeing with the

1 mechanically-cut mesh?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: I believe in my report, if
4 I may reference that, I explain what their goals were with
5 the review of the laser cut.

6 Do you want me to look at that?

7 BY MS. FITZPATRICK:

8 Q. Sure, take a look at that.

9 MR. DAVIS: While she's doing that, I'm
10 going to lower this blind. The sun is starting to -- over
11 here killing me.

12 MS. FITZPATRICK: It's starting to warm
13 up.

14 THE WITNESS: You want me to proceed?

15 BY MS. FITZPATRICK:

16 Q. Yes, please.

17 A. On page 19.

18 Q. Let me get there. Uh-huh.

19 A. In this particular report that I've
20 referenced, they said it was determined that the process
21 modifications to be made increased product yields, reduced
22 cycle time and also reduced possible fraying of the mesh.

23 Q. Okay.

24 A. But may I consult with counsel on something,

1 please?

2 Q. Not in the middle of a line of questions,
3 substantively.

4 A. Okay.

5 Q. Let's mark this as Exhibit 11.

6 (Whereupon, Exhibit 11 was marked.)

7 BY MS. FITZPATRICK:

8 Q. You have in front of you Exhibit Number 11.

9 Have you looked at this document before?

10 You've seen it?

11 A. I don't specifically recall it. Typically, I
12 can form an image of it, but I may have. I cannot
13 specifically recall it.

14 Q. Okay. If you've looked at it, it would be in
15 your reliance list that you provided?

16 A. Yes, I just can't recall it.

17 Q. Okay. Well, let's just take a quick look at
18 this. I want to direct you to the -- let me give you a
19 second to read through it.

20 A. Thank you.

21 MR. COMBS: This is marked?

22 MS. FITZPATRICK: Yeah, it's 11.

23 THE WITNESS: Okay. I'm ready.

24

1 BY MS. FITZPATRICK:

2 Q. Okay. And as best I can tell, this came out
3 somewhere around 2006, according to the first paragraph;
4 correct?

5 A. It would be in that time frame, I guess.

6 Q. And is it fair to say what's reflected here is
7 that Ethicon had looked at the impact of cutting the TVT
8 mesh using a laser cut instead of the mechanical cut?

9 A. They did, indeed, do that.

10 Q. Okay. And looking at the middle paragraph in
11 bold, bolded, Ethicon found that the laser cutting reduced
12 particulate loss; is that right?

13 A. He says this, but I must qualify my answer.

14 Q. Sure.

15 A. If you notice, he's referencing the clinical
16 expert report on the back page.

17 Q. Uh-huh.

18 A. And when I went to the clinical expert report,
19 it actually referenced the verification testing.

20 Q. Okay.

21 A. And I point that out in -- on page 20 in my
22 document.

23 Q. Okay.

24 A. And when I read the actual technical testing

1 report, the average amount of particles were less. It is
2 correct to say that they're less. It's the average
3 amount. When you completely read the report. It says
4 there's no statistical difference in the particulate loss.

5 And so in this circumstance, this person by
6 quoting the clinical expert report, he's making a
7 reference to the statement that was made in that report
8 that says that the average was reduced, but the average
9 amount was not statistically significantly different in
10 particulates. If you care to go to those reports, you
11 can see the specifics about the product loss.

12 Q. Okay. Well, this is written by the product
13 director from Continence Health; correct?

14 A. That's what it says his title is.

15 Q. Okay. And it's actually two people there;
16 correct?

17 A. Uh-huh.

18 Q. And it's been put out by Ethicon Women's
19 Health and Urology as a Product Pointer; correct?

20 A. Well, it says "Not for Distribution," so I
21 don't know if it was actually put out to anybody.

22 Q. Well, look at the first page.

23 A. Yes.

24 Q. It's written by Ethicon Women's Health and

1 Urology; correct?

2 A. But this says "Not for Distribution." I don't
3 know who -- to whom it -- for all I know, this could be a
4 draft. I don't know who put it out or if it went out. It
5 says --

6 Q. It says "For Internal Use;" correct?

7 A. Right, right. So I don't know who received
8 it.

9 Q. So you think there's a possibility that this
10 was written and one copy was put in somebody's drawer and
11 it was never meant for anything else beyond that?

12 MR. DAVIS: Object to form.

13 THE WITNESS: I can't say one way or the
14 other, ma'am, because it's not signed on here.

15 BY MS. FITZPATRICK:

16 Q. Fair enough.

17 A. So I don't know the pedigree of document.

18 Q. All right. Fair enough. Were they wrong when
19 they said, "We reduced particulate loss"?

20 A. Ma'am, as I explained, the report -- the
21 actual report said that the averages, when you look at the
22 averages, the averages -- the average amount of particles
23 was reduced, but that averages were not statistically
24 significant.

1 Q. Is this a correct statement or not? That's
2 all I want to know. It's yes or no.

3 A. It's not a precise statement.

4 Q. So you would draft this statement differently?

5 A. I can't say if I would or wouldn't. I'm
6 explaining to you that it isn't precise.

7 Q. Okay. But it's, at least, written here by
8 Ethicon; correct?

9 A. It appears to be so.

10 Q. It's at least something that was -- purports
11 to be written by product directors who are in charge of
12 the TVT laser cut and the TVT-0 laser cut; correct?

13 A. I believe so.

14 Q. Okay. And they state that they reduced
15 particulate loss by going from mechanical cut to laser
16 cut; correct?

17 A. Ma'am, he's quoting the CER report.

18 Q. That's what he wrote; isn't it?

19 A. Again, I don't know any more than I've already
20 told you about this document.

21 Q. Is that what he wrote?

22 A. He wrote, "We found by doing so." Yes, you
23 can quote him.

24 Q. "We reduced particulate loss, as well as the

1 potential for mesh fraying."

2 Did I read that correctly?

3 A. He wrote that.

4 Q. Okay. And in addition, if you go to the
5 second paragraph from the end, it says that "The laser-cut
6 mesh will be available for you to sell as needed,
7 particularly to customers that have voiced concerns
8 regarding particle loss and fraying;" correct?

9 A. That's what it says.

10 Q. And a fair assumption, based on that, is that
11 Ethicon had received complaints from certain physicians
12 concerning particle loss and fraying of the
13 mechanically-cut mesh; correct?

14 MR. DAVIS: Object to the form.

15 THE WITNESS: I'm sorry, I can't say
16 that I would characterize them as complaints. I can't
17 recall that specifically. There's a difference between a
18 customer response and a complaint, and I'd have to check
19 the accuracy of whether it was -- the information came in
20 as complaints, or if they were just general customer
21 comments back.

22 BY MS. FITZPATRICK:

23 Q. Okay.

24 A. I can't recall that.

1 Q. Well, using the word "concern," which is their
2 word.

3 A. Uh-huh.

4 Q. Concerns aren't usually just run-of-the-mill
5 general consumer comments; correct?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: Actually, they can be
8 anything. We make a very clear distinction between
9 an allegation of deficiency about the product being a
10 complaint, and there -- oftentimes, physicians make
11 suggestions for improvements, and they're not complaints;
12 they're just different ideas and suggestions.

13 BY MS. FITZPATRICK:

14 Q. So sitting here today, after you've been paid
15 almost \$60,000 by Ethicon and you look at an Ethicon
16 document that says that "customers that have voiced
17 concerns regarding particle loss and fraying," it's your
18 position that you don't know whether they really had a
19 concern or a complaint about the product?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: You specifically -- thank
22 you. You specifically asked me a question about
23 complaints. You were attributing this information to
24 complaints, and I was trying to clarify to you that

1 when I use the word "complaints," I'm very specific
2 within the context of my work as to whether it's a
3 complaint or not, and I would have to check the record
4 to see if there are specific complaints or if these
5 are suggestions and concerns and a suggestion.

6 So I can't take from this document what you
7 said; okay?

8 BY MS. FITZPATRICK:

9 Q. So let -- let's just be very clear on the
10 record.

11 You draw a distinction between the word
12 expressing a "concern" and a "complaint." You consider
13 those two different things?

14 A. They may or may not be. A complaint is a very
15 specific thing.

16 Q. And so after \$60,000 from Ethicon, you don't
17 know whether physicians were voicing complaints or
18 concerns regarding particle loss and fraying attributable
19 to the mechanically-cut device that's attributable -- or
20 that is at issue in this litigation; you just don't know?

21 A. Ma'am, I've had a --

22 MR. DAVIS: Wait, wait, wait. Object to
23 the form.

24 THE WITNESS: I have read many, many,

1 many complaint documents, and I have read many, many, many
2 other documents. I was trying to be specific to answer
3 your question, and if you'd like to repeat your original
4 question, I can explain to you better why I was concerned
5 with the way you formed it.

6 BY MS. FITZPATRICK:

7 Q. I don't want to get into a word game.

8 A. I'm not trying to.

9 Q. So let me just go back to this.

10 Voicing concerns is not a favorable
11 observation of a product; correct?

12 MR. DAVIS: Object to form.

13 BY MS. FITZPATRICK:

14 Q. General real world here. If someone voices a
15 concern to you, it's not a compliment, it's not a
16 favorable commentary on the product.

17 You know that; right?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: In my own personal
20 experience, when someone expresses a concern to me, they
21 may be concerned for my health, for my benefit, the way
22 I'm doing or not doing something. That doesn't mean
23 they're complaining to me about what I'm doing. So I
24 have to -- in my line of work, I have to be specific

1 about the term "complaint."

2 BY MS. FITZPATRICK:

3 Q. This is a negative comment.

4 A. Where?

5 MR. DAVIS: Object to form.

6 BY MS. FITZPATRICK:

7 Q. About the particle loss from the
8 mechanically-cut mesh; right?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: Please, would you be
11 specific where you're seeing the negative comment?

12 BY MS. FITZPATRICK:

13 Q. Voicing "concerns regarding particle loss and
14 fraying."

15 MR. DAVIS: Object to the form.

16 BY MS. FITZPATRICK:

17 Q. You don't see that as a negative comment? You
18 think it might actually be positive?

19 A. Excuse me, I'm trying to get to the section of
20 the document that you're looking at.

21 Q. Same section we've been looking at for the
22 last 10 minutes.

23 MR. DAVIS: And I object to the form.

24 THE WITNESS: If I take this sentence,

1 this person is expressing that for those customers who
2 have either voiced a concern for particle loss or voiced a
3 concern for fraying this product will be available. It
4 is not specifically stating that these customers have made
5 a complaint, and this is the distinction I was trying to
6 make when you asked me the question the first time.

7 BY MS. FITZPATRICK:

8 Q. You said "or." Where is the word "or" in that
9 sentence?

10 A. It's implicit in the sentence because of the
11 way the sentence is constructed.

12 Q. I read "and." And "and" and "or" are two
13 different words; right?

14 MR. DAVIS: Object to the form.

15 BY MS. FITZPATRICK:

16 Q. So where do you see "or"?

17 A. It can be either/or; particle loss and/or
18 fraying.

19 Q. That's not what this document says; does it?

20 A. It does not say that, but the context is that
21 those customers could have concerns for either, or both,
22 by the construction of the sentence.

23 Q. Does it say "or" anywhere?

24 MR. DAVIS: Object to the form;

1 argumentative.

2 THE WITNESS: I won't argue with you
3 about the sentence.

4 BY MS. FITZPATRICK:

5 Q. Okay. Well, you said "or," and I just want to
6 know where you got "or," because I'm reading "and."

7 MR. DAVIS: Object to the form;
8 argumentative.

9 THE WITNESS: I suppose there could be
10 some customers who voice both concerns at the same time.
11 I can't say.

12 BY MS. FITZPATRICK:

13 Q. But the bottom line here, you have to agree
14 with me, Ms. Duncan, some physicians were telling Ethicon
15 that they had concerns about the fact that the
16 mechanically-cut mesh had particle loss and fraying;
17 right?

18 MR. DAVIS: Before you answer, I'm going
19 to instruct the witness, you don't have to agree with
20 anything. You're here to answer questions truthfully to
21 the best of your ability. You're not required to agree
22 with anything.

23 THE WITNESS: In this context, I
24 can't answer your question. This was a sales piece. I

1 don't even know if it got out the door, and so if you
2 want to construe that sentence in the way you said, I
3 have no way to counter what you've been saying.

4 BY MS. FITZPATRICK:

5 Q. Let's leave it at that.

6 You've never published on stress urinary
7 incontinence; right?

8 A. No, ma'am.

9 Q. And you've never published anything regarding
10 any of the risks that are associated with the stress
11 urinary incontinence device; have you?

12 A. No, ma'am.

13 Q. And none of the presentations that are listed
14 in your CV involve surgical mesh; correct?

15 A. Your sentence is in -- your -- the way you
16 have phrased that question, I can't answer it the way
17 you've asked it. If you want to ask it again, I'll try
18 to clarify.

19 Q. Well, am I correct or not?

20 A. Your sentence -- your question is something
21 not correct.

22 Q. Are any of the presentations that are listed
23 in your CV involving surgical mesh?

24 A. Surgical mesh is a term of art with the FDA,

1 and it incorporates a wide variety of meshes, not just
2 urinary incontinence meshes, and I can look at my CV and
3 tell you if any of them included surgical mesh or not.

4 Q. Sure.

5 A. If that's what you'd like me to do.

6 Q. That would be great.

7 A. In my presentations and speeches "Leaping the
8 Hurdles of Medical Textile Devices," that would have been
9 incorporating, as a generic product, surgical meshes. In
10 the context of the FDA guidance document on what is a
11 surgical mesh, I probably touched on that in that
12 presentation.

13 "Biomaterials Qualification and Selection for
14 Spinal Implants," I can't recall if that discussed meshes
15 or not. It is -- meshes are used in some spinal implants.

16 I believe that's the only two that would
17 have -- presentations and speeches that would have had
18 specific reference to surgical meshes.

19 Q. Okay. Did either of those presentations
20 involve PROLENE mesh?

21 A. Not as a specifically-named product, no.

22 Q. Have you ever presented on the TVT product,
23 specifically?

24 A. No, ma'am.

1 Q. Have you ever presented on stress urinary
2 incontinence?

3 A. No, I have not made presentations on that.

4 Q. Have you ever presented on anything regarding
5 the risks that are associated with stress urinary
6 incontinence devices?

7 A. As a public presentation?

8 Q. Yes.

9 A. No, ma'am.

10 Q. Okay. Have any of the products that you've
11 consulted on involved products that treat stress urinary
12 incontinence?

13 A. Yes, ma'am.

14 Q. Okay. And which ones are those?

15 A. I consulted with a company that had a bulking
16 agent.

17 Q. Okay. And what company was that?

18 A. I can't recall the company name. I think it
19 was Carbon something. I can't remember the name.

20 Q. And how far ago was that?

21 A. Maybe 10 years.

22 Q. Okay. Anything else?

23 A. Yes, I consulted with a company that made a
24 urinary incontinence insert device.

1 Q. And when was that?

2 A. That product was -- the company name was
3 ContiCare.

4 Q. C-O-N-T-I-C-A-R-E?

5 A. Yes.

6 Q. Okay. And when was that?

7 A. Again, about 10 years ago.

8 Q. And can you describe that device to me?

9 A. It was an insert.

10 Q. Into the --

11 A. Urethra.

12 Q. Urethra?

13 A. Yeah.

14 Q. Okay.

15 A. Then there was another --

16 Q. Was that ever marketed?

17 A. No, we were in clinical trials.

18 Q. Okay. And it never made it out of the
19 clinical trials to market?

20 A. Ran out of money.

21 Q. Okay. And anything else?

22 A. Another urinary incontinence device that was
23 almost 20 years ago, and I can't recall the name. It was
24 a valved catheter.

1 Q. Okay.

2 A. And I consulted with Empi. That company was
3 local, and their name has -- has been changed. I don't
4 know if Empi's still exists.

5 Q. I --

6 A. E-M-P-I. They had a stimulator.

7 Q. Okay. Anything else you worked with on stress
8 urinary incontinence over the years?

9 A. Not stress urinary incontinence, no.

10 Q. Okay. Have any of the devices that you've
11 worked on involved pelvic organ prolapse?

12 A. We might not have been specifically indicating
13 or contraindicating why the patient had the stress
14 incontinence.

15 Q. Okay.

16 A. It was more of a symptomatic device.

17 Q. And what was that? I'm talking pelvic organ
18 prolapse, I'm sorry.

19 A. These were external devices. With the
20 exception of the bulking agent, all of these -- which is
21 an implanted product, but all of the other products are
22 dealing with the symptoms.

23 Q. Okay.

24 A. So the stimulating device, I'm not sure that I

1 recall that the specific reason a patient had stress
2 incontinence was stipulated. We -- the patients had to
3 undergo certain clinical testing, PAG, weight and
4 cystoscopy.

5 Q. Cystoscopy?

6 A. And if that condition existed, they were
7 candidates for the devices.

8 Q. Okay.

9 A. So specifically why they were having their
10 incontinence was -- we were typically not specifying that.
11 They just had to have an incontinence level at a
12 certain --

13 Q. Okay.

14 A. External devices.

15 Q. And those were for stress urinary
16 incontinence; correct?

17 A. Yes, ma'am.

18 Q. So I want to flip, pelvic organ prolapse.

19 A. All right.

20 Q. Did you work on any devices --

21 A. No, ma'am.

22 Q. Okay. And have you ever seen the TVT device
23 before?

24 A. Not before this task, this assignment.

1 Q. In connection with the work that you've done
2 here, have you actually seen or held a TVT device?

3 A. Yes, ma'am.

4 Q. And do you know whether it was
5 mechanically-cut or laser cut?

6 A. I believe I've seen both.

7 Q. Okay. And how did you tell the difference
8 between the two?

9 A. I had a little magnifying glass.

10 Q. Okay. So it was visible to you under the
11 magnifying glass?

12 A. Right.

13 Q. And who provided those TVTs to you?

14 A. I believe counsel provided those.

15 Q. Okay. And did you also look at the trocar
16 devices that were used?

17 A. Just briefly to see how many were connected.

18 Q. Okay. And how about the instructions for use?

19 A. Yes, ma'am.

20 Q. So did you look at it as part of a whole kit
21 that the --

22 A. It was in the kit. It was in the kit.

23 Q. Did you specifically ask to see both the
24 mechanically-cut and the laser-cut meshes?

1 A. I didn't specifically ask for it. They were
2 given to me.

3 Q. Now, when you were initially -- how are you
4 doing?

5 MR. DAVIS: I think we ought to take a
6 break in about five more minutes. Find a good stopping
7 point.

8 MS. FITZPATRICK: Yeah, let me just get
9 through some of this stuff. It's only a couple of pages.
10 Let me just get through this, and then we'll take a break
11 for lunch.

12 MR. DAVIS: Okay.

13 BY MS. FITZPATRICK:

14 Q. When you were consulted by Ethicon's lawyers
15 for work in this case, what specifically were you asked to
16 do?

17 A. These are my words.

18 Q. Sure.

19 A. To do a due diligence review of the
20 documentation for the product from the time period of
21 the -- I guess I could characterize it as the licensure,
22 and then, subsequently, we cut off the review at the
23 TVT-O.

24 Q. And what date was that?

1 A. Which date?

2 Q. You said you cut off the review at the TVT-O.

3 A. Before the TVT-O. I probably looked at some
4 of the TVT-O documents before we made that determination,
5 so I -- I'm going to estimate that was late July.

6 Q. Wait, let me make sure that I'm following you
7 here.

8 You have looked at all of the risk assessment
9 and risk hazard assessment files related to the TVT-R;
10 correct?

11 A. Yes, ma'am.

12 Q. And that's without a date limitation; is that
13 correct?

14 A. I would say that's correct.

15 Q. Okay. And what you excluded from your
16 analysis were documents related to the TVT-O; is that
17 right?

18 A. If they specifically said they were only for
19 TVT-O or AA, then I didn't spend any further time on them.
20 If I had seen them, I didn't go back and work on them at
21 all.

22 Q. Okay. So you didn't look at the TVT-O
23 specific or the TVT-AA specific risk documents; is that
24 right?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: I can't recall if I did or
3 didn't. Do you have my timeline there?

4 BY MS. FITZPATRICK:

5 Q. Sure. Is this the one, 7?

6 A. Yeah, and my other notes there.

7 Q. Yes.

8 A. So as you'll see here, I was -- this was
9 my initial activity to try to put documents on a timeline.
10 So I may have, apparently, looked at some of these
11 documents because I was trying to put them all on a
12 respective timeline.

13 Q. Okay.

14 A. And then, basically, later on, I said anything
15 below this line I don't need to continue to look at.

16 Q. Okay. And that line looks like a 2010
17 TVT-O-PA; is that correct?

18 A. And I can't even recall what "PA" stands for.
19 My notes --

20 Q. I don't know, either.

21 A. I had looked at some -- very comprehensively
22 looked at documents, tried to put them on a timeline. And
23 then later, in a discussion, we said, "Oh, you don't need
24 to be specific with the TVT-O documents."

1 I don't have a copy of that, by the way.

2 Q. Sure. Why did you take the TVT-O document --
3 in fact, if I'm looking at this correct, up in this left
4 corner, you have "TVT-O" circled with an X through it and
5 "TVT Secur" with an X through it.

6 So you eliminated those two products from your
7 consideration for this?

8 A. For the report.

9 Q. Why did you do that?

10 A. The scope was limited.

11 Q. To the TVT-R; correct?

12 A. No, it was not limited to just TVT-R. It cut
13 off at TVT-O, and that's why -- basically, at that time,
14 put that line there.

15 Q. Okay. So the TV -- you knew that TVT-O was on
16 the market before 2010; correct?

17 A. Ma'am, the point I was making was that TVT-O
18 was not specifically -- now, again, if there are common
19 documents, I've looked through them.

20 Q. Okay.

21 A. Okay. But the scope of my review as a
22 comprehensive due diligence did not go out to TVT-O.

23 Q. Okay. And that's because it's a different
24 product -- different but related product to the TVT-R;

1 correct?

2 A. Because of just things you mentioned, there's
3 surgical instrumentation and the location of the mesh in
4 the body. And so the mesh is common, things that are
5 about the mesh are common, but specific device, I cut that
6 off.

7 Q. Okay. And that's the same with the TVT Secur
8 for the same reasons?

9 A. Yes, ma'am.

10 Q. Okay. How many times have you met with
11 counsel between the middle of July and when you submitted
12 your report in this case?

13 A. I think it was about six.

14 Q. Okay. Who did you meet with?

15 A. Well, I think I've mentioned their names.
16 I've met with Kim Moore, I've met with Chad Hutchinson,
17 I've met with Stephen Myers, I've met with Paul and Phil.
18 Can I have my copy of that?

19 Q. Sure.

20 A. I don't even have that anymore. Thank you.

21 Q. And about how many hours did you spend between
22 the middle of July and the time when you submitted your
23 report in this case?

24 A. I don't have the exact numbers, but I've

1 estimated 120.

2 Q. Did you bring any billing records with you
3 today?

4 A. I didn't bring any billing records. I
5 thought they were going to be provided, so I didn't bring
6 bring them.

7 Q. And that's something that you produced to
8 Ethicon's lawyers that I can get from them?

9 A. You can get them from them. They have copies.

10 Q. Okay. And who, besides yourself, at your
11 company worked on the report, if anyone?

12 A. I had some assistance from some interns in
13 printing and compiling the documents into binders, but the
14 report was specifically my own.

15 Q. Okay. And your report has an Exhibit A to it;
16 correct?

17 A. Yes, ma'am.

18 Q. Okay. And does that list represent the
19 universe of documents that you've reviewed in this case?

20 A. Yes, ma'am.

21 Q. And if you'd look at it, it's there.

22 A. Yes, ma'am.

23 Q. Have you looked at all of the documents that
24 are on that list?

1 A. It has been my endeavor to look at every one
2 of them. I -- believe it or not, yes.

3 Q. So you've read all of those documents?

4 A. I can't say I've read them all. I have
5 certainly scanned and looked at as many possible, yes.

6 Q. And where did you get that list of documents
7 from?

8 A. This list --

9 Q. Uh-huh.

10 A. -- was actually compiled on my behalf. I did
11 not type these all up.

12 MR. DAVIS: I'll help you out. My law
13 firm kept a record of everything that she asked for and
14 has provided, and we provided this for her.

15 MS. FITZPATRICK: And you generated
16 that, Exhibit A, which represents everything that you --
17 your firm has provided to Ms. Duncan?

18 MR. DAVIS: With one exception. She
19 went out and got some things on her own and posted them,
20 and we added those to the list.

21 BY MS. FITZPATRICK:

22 Q. Okay. Were there any documents that you were
23 provided but you didn't actually put on your reliance
24 list?

1 A. Not to my knowledge.

2 Q. Okay. Have you spoken with any other experts
3 in this litigation?

4 A. No, ma'am, I have not.

5 Q. Okay. Have you published any of the opinions
6 concerning the TVT devices that are the subject of your
7 expert report?

8 A. No, certainly not.

9 Q. Okay. Have you tested any of these opinions?

10 A. I would say I have tested them after the fact;
11 after I've written my report, I have tested them in a very
12 specific way.

13 Q. Okay. Tell me what way that is.

14 A. Specifically, I considered the clinical
15 literature, and specifically, I considered the information
16 in the AUGS statement. The AUGS document was a part of my
17 reading but not a part of my review of due diligence,
18 because this came out afterwards, and so it's supportive
19 of the conclusions that I made, and I consider that
20 testing, but I -- maybe you consider testing in a
21 different way. I'm not sure, maybe, what you mean.

22 Q. That's okay. Have the opinions that you set
23 forth in your report been reviewed by anyone?

24 A. When I produced the report, we reviewed it.

1 Counsel reviewed it with me, yes.

2 Q. Okay. So apart from Ethicon's lawyers, have
3 you reviewed that report with anybody else?

4 A. No, ma'am.

5 Q. Okay. Who wrote that report?

6 A. I did.

7 Q. And you sat down, and everything that's in
8 there, you typed out yourself?

9 A. With the exception, I didn't put the footnotes
10 in the document. I put my references specific in the
11 paragraph, and then they were transposed for me.

12 Q. Okay.

13 A. Okay.

14 Q. And did you receive any edits to your drafts
15 from Ethicon's lawyers?

16 A. We reviewed and I edited the document.

17 Q. Okay. In connection with the conversations
18 that you had?

19 A. We had conversations about my conclusions, and
20 in some cases, because I'd written rather fast, some of
21 the sentences needed improvement for grammar, but the
22 content and the conclusions are my own.

23 Q. Okay. And would you agree with me that it's
24 possible for another person who has expertise in risk

1 management to review the same materials that you've
2 reviewed and come to a different conclusion than you've
3 come to?

4 A. Apparently, it has happened because Ms. Wilson
5 has a different opinion.

6 Q. And people in your field can have different
7 opinions on these subjects; correct?

8 A. I would have to agree with that.

9 Q. And how much of your opinion is premised on
10 Ethicon's own conclusions regarding the quality management
11 system?

12 A. I did not have any conversations or review any
13 written statements by the Ethicon people with the
14 exception of when Ethicon did an audit and I read those
15 audits.

16 Q. Okay. And the -- all of the opinions that are
17 contained in your report were developed specifically for
18 this litigation; right?

19 A. Yes, ma'am.

20 MR. DAVIS: You getting near that --

21 MS. FITZPATRICK: Yeah, let's take --
22 why don't we take a lunch break now.

23 MR. DAVIS: If you have --

24 MS. FITZPATRICK: No. You know, I'm at

1 a good place for a break, so this is a good time to do
2 that.

3 (Whereupon, a recess was taken from
4 12:39 p.m. to 1:42 p.m.)

5 BY MS. FITZPATRICK:

6 Q. Ms. Duncan, what does RAC stands for?

7 A. Regulatory Affairs Certification.

8 Q. And what is a Regulatory Affairs
9 Certification?

10 A. It's issued by the Regulatory Affairs
11 Professional Society based on qualifications and testing.

12 Q. Okay. And you'd agree with me that your
13 company specializes in regulatory strategies; correct?

14 A. We do that, but we do many other things, as
15 well.

16 Q. Okay. And what -- can you tell me what
17 regulatory strategies is? What does that mean?

18 A. Well, it's -- from time to time, either a new
19 medical product or an existing product may need to be --
20 the people developing it may need to be aware of the
21 regulations and standards that would apply to the product.
22 So I try to assess the product that they're hoping to
23 produce or the modification they want to make and give
24 them an advance assessment of what kind of work they

1 would have to do in development and testing, and what
2 kind of application they might make to respective
3 agencies.

4 Q. And do you help medical device companies
5 prepare regulatory paperwork?

6 A. That's part of what I do.

7 Q. Okay. And in preparing your expert report in
8 this case, were any of the materials that you considered
9 in forming your opinions part of regulatory submissions
10 concerning the --

11 A. Just let him pass (noise).

12 Q. Sure.

13 A. Okay. Start again, thank you.

14 Q. And were any of the materials that you
15 considered in forming your opinions in this case part of
16 the regulatory submissions relating to the TVT-R product?

17 A. I'm not understanding the question. Part
18 of --

19 Q. Regulatory submissions from Ethicon regarding
20 the TVT-R product?

21 A. Were those a part of my assessment?

22 Q. Yes.

23 A. Yes.

24 Q. And did you rely solely on regulatory

1 submission documents when you were preparing your opinions
2 in this case?

3 A. No.

4 Q. And is it possible for you to reach the
5 conclusions that you reached in this case concerning the
6 adequacy of the design processes and due diligence taken
7 by Ethicon without relying on regulatory submission
8 documents?

9 A. Is it possible -- I'm sorry, the length of the
10 question, I kind of lost the train. Say it again.

11 Q. Is it possible for you to reach the
12 conclusions that you reached in this case concerning the
13 adequacy of the design processes and due diligence taken
14 by Ethicon without relying on regulatory submission
15 documents?

16 A. It's possible, yes.

17 Q. Do you believe that the only reason that a
18 company complies with ISO standards is to comply with
19 regulatory standards?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: There are many ISO
22 standards so you have to be more specific.

23 BY MS. FITZPATRICK:

24 Q. The ISO standards that are mentioned in your

1 report.

2 A. Again, there are several that are mentioned in
3 the report, so can you be specific?

4 Q. Any of them. I mean, if you want to go
5 through all of them, we can go through all of them.

6 A. What's the question, again, then?

7 MR. DAVIS: The problem is, it may or
8 may not be the same, depending on which one you're talking
9 about.

10 BY MS. FITZPATRICK:

11 Q. Okay. You mentioned a number of standards --

12 A. What page?

13 Q. It doesn't -- I mean, I'm on page 7. You
14 don't have to be on page 7.

15 You mention a number of ISO standards in your
16 report; correct?

17 A. There are several.

18 Q. Okay. And which ISO standards did you cite in
19 support of your opinions that you have offered in this
20 case?

21 A. Did I cite, actually, or consider?

22 Q. Cite.

23 A. I believe we cited 13485 and multiple versions
24 of that, and also the ISO 19 -- 14971, versions of that.

1 And I can't recall if I brought up -- I don't think I
2 brought up compatibility standards. So that would be
3 the two specific ones I believe we discussed in the
4 report.

5 Q. Okay. So let's go back.

6 Do you have an opinion whether the only reason
7 that a company would comply with ISO Section 13485 is to
8 comply with the regulatory requirement?

9 A. I can't say it's the only reason.

10 Q. Okay. And do you believe that the only reason
11 that a company would comply with ISO Section 14971 was --
12 or is to comply with the regulatory requirement?

13 A. 14971 is actually a voluntary standard, so it
14 is not an obligatory standard.

15 Q. Okay. And you would agree with me that it is
16 possible to reach opinions concerning the adequacy of --
17 let me make sure I'm using your words -- qualified design
18 and due diligence without reference to the regulatory
19 process; right?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: I lost track of your
22 agreement question, there.

23 BY MS. FITZPATRICK:

24 Q. Would you agree with me that it's possible to

1 reach opinions concerning the adequacy of the qualified
2 design and due diligence without reference to the
3 regulatory process?

4 A. Is it possible to reach conclusions based
5 on -- I'm so sorry, I --

6 Q. There's a regulatory pathway; correct, for
7 preparation?

8 MR. DAVIS: Object to the form.

9 BY MS. FITZPATRICK:

10 Q. Are you okay?

11 A. Yeah, you're losing me with your questions
12 like --

13 Q. Okay.

14 A. I'm trying to follow you, but --

15 Q. We're here talking about a medical device
16 manufacturer; right?

17 A. Right.

18 Q. And you understand we're talking about
19 Ethicon?

20 A. Right, you've got too many commas in your
21 questions for me. Maybe that's -- my problem is
22 tracking your question.

23 Q. I'll try to cut them down a little bit for
24 you.

1 A. Thank you. That would be good. That would be
2 good.

3 Q. And we're talking about the Ethicon TVT-R
4 mechanically-cut device; correct?

5 A. Yes.

6 Q. And we're talking about the standards that
7 Ethicon did or didn't adhere to in adopting the design of
8 that product and risk hazards that they did subsequent to
9 the marketing of that product; correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: I'm sorry, I can't answer
12 the question because you lose -- I lose track of you in
13 the middle of it.

14 BY MS. FITZPATRICK:

15 Q. Why don't -- if you're having trouble
16 concentrating, let me know and we'll --

17 A. It's not the concentrating.

18 Q. Go ahead and read the question back.

19 A. Can I see it and see if that would help me to
20 read it, because the way -- it's something about the way
21 you're speaking that I'm losing track in the middle of the
22 sentence.

23 Q. No, I'm just surprised that this happened
24 after lunch. You didn't have a problem this morning, but

1 maybe we all get that little afternoon lull. So maybe if
2 the court reporter tries it with you, we can see where
3 that goes.

4 MR. DAVIS: Object to the form.

5 (The record was read back.)

6 THE WITNESS: We're talking about --
7 we're talking about.

8 BY MS. FITZPATRICK:

9 Q. What do you think we're talking about today?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Ma'am, I'm trying to
12 follow your questions to the best of my ability, and
13 they're so convoluted, I lose track of what you're after
14 in the middle of the sentence. Can you break them down --

15 BY MS. FITZPATRICK:

16 Q. Sure.

17 A. -- into maybe shorter questions?

18 Q. What do you think we're talking about today?

19 A. You don't have to talk like that to me.

20 Q. I'm asking a simple question.

21 A. I'm doing my very best to try and answer --

22 Q. You had no problem answering before an
23 hour-long break with your lawyer, so I'm trying to get an
24 understanding.

1 What do you think we're talking about today?

2 MR. DAVIS: Object to the form.

3 THE WITNESS: Yes, I'm insulted, too.

4 I am trying to understand --

5 BY MS. FITZPATRICK:

6 Q. So am I, but that's okay.

7 A. I'm trying to understand your questions.

8 Q. What didn't you understand about the question
9 I just asked you?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Because it was so
12 convoluted, I couldn't keep track of what you were saying.

13 BY MS. FITZPATRICK:

14 Q. Let's go to the pending question.

15 What do you think we're talking about today?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: My report, my due
18 diligence work on this project. That's what we're talking
19 about.

20 BY MS. FITZPATRICK:

21 Q. We're talking about Ethicon; correct?

22 A. Yes, ma'am.

23 Q. We're talking about the TVT-R mechanical cut;
24 correct?

1 A. I didn't limit my report to that, but if you
2 want to limit it to that, that's fine.

3 Q. Okay. We're talking about the due diligence
4 that you believe Ethicon did at the time they acquired the
5 TVT-R mechanical cut; correct?

6 A. Correct.

7 Q. And we're talking about the risk hazards that
8 Ethicon engaged in after they acquired and marketed the
9 TVT-R mechanical cut.

10 You understand that?

11 A. No, because what you said was Ethicon's risk
12 hazards that they engaged in. That phrase has -- is odd
13 because I don't think that Ethicon engaged in hazards.

14 Q. Okay.

15 A. Is that what you're asking me; did Ethicon
16 engage in hazards?

17 Q. Did they engage in risk-hazard analysis,
18 Ms. Duncan? Do you know that?

19 A. That isn't what you said. You said they
20 engaged in risk-hazards.

21 Q. Okay.

22 A. So are you speaking of hazard analysis and
23 risk assessment?

24 Q. You tell me. It's your report. Is that

1 what -- I'm happy to use whatever phrases you want me to
2 use.

3 MR. DAVIS: Object to the form.

4 BY MS. FITZPATRICK:

5 Q. I'm trying to get us on the same page. You
6 tell me the terms and I'm happy to use them.

7 So what is it that --

8 MR. DAVIS: Object to the form.

9 THE WITNESS: You asked me if Ethicon
10 engaged in hazards.

11 BY MS. FITZPATRICK:

12 Q. No, we've got to move on.

13 A. Okay.

14 Q. My question to you is, what terms do you want
15 to use, and I'll use them?

16 MR. DAVIS: Object to the form. For
17 what purpose?

18 MS. FITZPATRICK: The purpose of the
19 conversation that we're having.

20 THE WITNESS: We got to --

21 BY MS. FITZPATRICK:

22 Q. Ms. Duncan, did something happen at lunch
23 today?

24 MR. DAVIS: Object to the form.

1 MR. COMBS: That's rude.

2 MR. DAVIS: That's rude.

3 MR. COMBS: This is rude.

4 MS. FITZPATRICK: You're rude. I think
5 this is extraordinarily rude, and I do question what
6 happened at lunch, but we will try to move on.

7 MR. COMBS: Get a Judge on the phone.
8 If you're insulting us and saying we did something at
9 lunch, then get a Judge on the phone.

10 MS. FITZPATRICK: Go right ahead.

11 MR. COMBS: You're the one who's making
12 the insults, and you're insulting her.

13 MS. FITZPATRICK: I know that you're a
14 little unnerved to have a deposition going, but you guys
15 might want to take it down and not show your hand quite as
16 much. Let's just get back to the question.

17 BY MS. FITZPATRICK:

18 Q. Due diligence; do you know what that means?

19 A. Yes, ma'am, I do.

20 Q. Okay. Tell me what that means.

21 A. The way I work, due diligence is to assess the
22 pattern and practices of the company and the individuals
23 with respect to, number one, the time frame we're working
24 in; number two, the standards and regulations that were

1 applicable in that time frame; the procedures that reflect
2 those standards and regulations in that time frame; and
3 the practices of the individuals with respect to those
4 procedures with respect to those regulations and
5 standards. So I think I am articulate.

6 Q. Okay. Well, we both --

7 A. I didn't have a stroke during lunch.

8 Q. We both think we're articulate, but maybe
9 we're just talking past each other.

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Okay.

12 BY MS. FITZPATRICK:

13 Q. Throughout your report, you know that you have
14 referenced, don't you, regulatory requirements; correct?

15 A. They are applicable for both Europe and the
16 U.S. and the standards that were cited in Ms. Wilson's
17 report and as a part of my due diligence. So they are
18 comprehensive to my report.

19 Q. We are clearly talking past each other, and
20 maybe you didn't understand my question.

21 A. Okay.

22 Q. So I'll try it again.

23 MR. DAVIS: Object to form.

24

1 BY MS. FITZPATRICK:

2 Q. Throughout your report, you know that you have
3 referenced regulatory requirements; correct?

4 A. The standards and regulatory requirements,
5 yes.

6 Q. And some of those regulatory requirements
7 relate to the FDA 510(k) clearance process; correct?

8 A. Some of those -- I'm sorry, some of those --
9 say it again.

10 Q. Some of those regulatory requirements relate
11 to the FDA 510(k) clearance process; correct?

12 A. Very little, actually. Most of what I relied
13 on was documentation that was not part of the 510(k).

14 Q. And would you agree with me that it is
15 possible to look at and assess a company's due diligence
16 without reference to its regulatory submissions?

17 A. I would think that to try to eliminate how the
18 company met regulatory requirements would be to omit a
19 significant portion of the work I would be looking at.

20 Q. Okay. So your -- you, in preparing this
21 report, have considered and included reliance on FDA
22 regulatory requirements; correct?

23 A. Not reliance on. I don't -- that's the part
24 of the question that I can't comprehend how you're trying

1 to use that in a sense.

2 Q. Okay. I'm going to read you your answer so
3 we're focused on what that answer is, and then hopefully
4 you can educate me.

5 Answer: "I would think that to try to
6 eliminate how the company met regulatory requirements
7 would be to omit a significant portion of the work I would
8 be looking at."

9 Did you omit -- or excuse me -- did you
10 eliminate how Ethicon met regulatory requirements in
11 preparation for your report today?

12 A. Did I omit them?

13 Q. Yes. "Eliminate" is your word.

14 Did you eliminate them?

15 A. I did not eliminate them or omit them.

16 Q. So you did include regulatory requirements as
17 the basis of your opinions?

18 A. No, right there, that's where you run off the
19 track, if I may say so.

20 Q. Sure.

21 A. So start again. Did I --

22 Q. I want to know how you think I ran off the
23 track.

24 You said you didn't eliminate regulatory

1 requirements when you prepared your report; correct?

2 A. Right.

3 Q. So did you rely on the regulatory requirements
4 when you prepared your report?

5 A. There's a difference between omitting them and
6 relying on them.

7 Q. Okay. Let's get --

8 A. I incorporated all of the findings.

9 Q. Excuse me, let me ask the question first.

10 A. Sorry.

11 Q. What do you say is the difference between
12 omitting and relying? What am I missing here?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: If I were to omit them, I
15 would not be comprehensive. As a part of due diligence,
16 we not only look at their compliance to standards and
17 procedures, we look at how those standards and procedures
18 were germane to the medical device regulations worldwide.

19 BY MS. FITZPATRICK:

20 Q. Using your words, did you look at how the
21 standards and procedures used by Ethicon were germane to
22 the medical device regulations worldwide?

23 A. I did.

24 Q. Okay. And in doing that, did you consider the

1 regulatory requirements by the FDA for medical devices?

2 A. I would have had to in order to do my job.

3 Q. Okay. Is there any way you -- you say in
4 order to do your job.

5 Could you have done your job without reference
6 to the FDA regulatory requirements?

7 A. If we were looking only at the due diligence
8 for a European product, I could have eliminated the FDA.

9 Q. But we're not talking about a European product
10 here. We're talking about a product that was marketed in
11 the United States.

12 You do understand that; don't you?

13 A. It was marketed worldwide. That's why there's
14 so many languages.

15 Q. Including in the United States. You
16 understand that; right?

17 A. Yes.

18 Q. And you understand that this litigation is
19 filed in the United States; correct?

20 A. Yes.

21 Q. And you understand it's brought by women from
22 the United States; correct?

23 A. If you say so. I don't know these people.

24 Q. And you never thought to ask Ethicon's lawyers

1 anything about the underlying merits of the lawsuit?

2 A. Ma'am, the underlying merits of the lawsuit
3 have nothing to do with the scope of my work.

4 Q. Interesting. Okay. So we are talking about a
5 product that was marketed in the United States; correct?

6 A. Yes.

7 Q. And so because it is marketed in the United
8 States and because the lawsuit arises out of actions taken
9 by Ethicon in the United States; do you understand that?

10 A. Yes.

11 Q. Okay. You looked at and considered the FDA
12 regulatory requirements in reaching your opinions in this
13 case; correct?

14 A. With respect to the compliance of the company
15 to standards that were recognized at the time that I
16 was reviewing. So in every instance, as I reviewed each
17 phase, I had to appreciate the standards, guidances and
18 regulations; I had to understand how those were translated
19 into procedures and how the personnel behaved accordingly.

20 Q. Okay. Now, so we don't get into any confusion
21 about the terms that I use, let me go back and find one of
22 your answers for a second.

23 I asked you earlier, "Could you have done your
24 job in producing this report without reference to the FDA

1 regulatory requirements?" That was my exact question.

2 And your response was, "If you were looking
3 only at the due diligence for a European product, I could
4 have eliminated the FDA;" correct?

5 A. That's still correct.

6 Q. We're looking at the due diligence of a
7 United States product here; correct?

8 A. Yes, ma'am.

9 Q. So you could not reach opinions about the due
10 diligence for a United States product like the one at
11 issue here without reference to the FDA requirements.

12 Is that what you're saying?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: In order to know if the
15 personnel did the right thing, I had to look at
16 procedures, and those procedures had to conform to the
17 requirements imposed on Ethicon within the United States,
18 and that was directed by way of guidance documents,
19 standards, and regulations. There's no way to isolate
20 just standards and just regulations because they are
21 intertwined.

22 BY MS. FITZPATRICK:

23 Q. So the FDA regulations concerning medical
24 devices are intertwined with all of the opinions that you

1 have reached concerning Ethicon's conduct regarding the
2 TVT-R in your report?

3 A. No, I didn't say that.

4 Q. Okay. Tell me where I'm wrong.

5 A. I said that in order to do due diligence in
6 each of the phases, we have to appreciate, again, how the
7 personnel behaved and did their job, what their
8 deliverables were, what documents they produced and what
9 they look like. I take it, then, back to the procedures
10 that were required of them at that time, and those
11 procedures are derived directly from all of these things:
12 the standards, the regulations and the guidance documents
13 that are current at the time I am looking at each phase.
14 That's the due diligence I have to do.

15 Q. I'm not sure what you're not understanding
16 about the question, but I'll try it again.

17 MR. DAVIS: Object to the form.

18 BY MS. FITZPATRICK:

19 Q. Can you do what you did without -- let's see
20 what word you used -- looking at and relying on the FDA
21 regulations concerning medical devices?

22 A. "Relying on," that's the word I think I
23 have -- the distinction you're making with "relying on."

24 I have to assess their behavior, their work,

1 their output in the context of what was happening at the
2 time I'm looking. So if I'm looking at due diligence
3 of a license, I look at what's current at that time with
4 respect to procedures that derive from standards in
5 guidance documents and regulations.

6 Q. Okay. You keep giving me the same answer.

7 A. It's the same answer?

8 Q. Well, you're not answering the question.

9 A. I'm sorry, I'm trying my best.

10 Q. So let me try this again.

11 MR. DAVIS: Object to the form.

12 MR. WALLACE: You're talking over her.

13 THE WITNESS: Thank you.

14 BY MS. FITZPATRICK:

15 Q. Can you do what you did in this report without
16 looking at and considering the FDA regulations concerning
17 medical devices?

18 A. You have to consider them.

19 Q. Okay. And you considered the FDA regulations
20 concerning medical devices in your report and in your
21 opinions that you reached in this case; right?

22 A. As one of many things that I considered.

23 Q. And you're not able to issue this report
24 without considering the FDA regulations.

1 Is that your testimony?

2 A. No, I could go back and revise the report
3 and leave out FDA regulations, but it would be less than
4 a diligent job on my part because I have to be present
5 with respect to standards and regulations and best
6 practices that are current in each of these phases.

7 So if you would want me to go back and revise
8 the report, for example, and take out just FDA
9 regulations, it would be peculiar, at best.

10 Q. Would it be a different report?

11 A. I can't say without attempting to do it. It
12 wouldn't be what I normally do as a part of due diligence.

13 Q. Okay. And it wouldn't be --

14 A. Can I give you an example?

15 Q. Hang on. Yes, you can, but let me make sure
16 that I'm understanding.

17 A. Okay.

18 Q. Because you and I seem to have lost --

19 A. Our rapport?

20 Q. I don't want to say rapport, but we seem to be
21 talking past each other.

22 The report, as drafted, has intertwined
23 throughout it consideration of the FDA requirements for
24 medical devices; correct?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: From phase to phase,
3 there may be portions. That's a very broad question,
4 so I have to answer you broadly.

5 BY MS. FITZPATRICK:

6 Q. Let me read the question back because I'm not
7 sure why we're having so much trouble now.

8 The report, as drafted, has consideration
9 throughout your opinions of the FDA requirements for
10 medical devices; isn't that right?

11 MR. DAVIS: Object to form.

12 THE WITNESS: Could you give me an
13 example where you see that, and then maybe that will help?

14 BY MS. FITZPATRICK:

15 Q. Well, I just happened to open a page, 17.

16 A. Okay.

17 Q. We have reference to the 510(k) application,
18 510(k) clearance, 510(k) application requirements.

19 A. I'm sorry, what page was that?

20 Q. We're on page 17, the middle paragraph. Just
21 randomly happened to open to this page.

22 A. Okay.

23 Q. Right in the middle, you're talking about the
24 510(k) application and clearance process.

1 That's part of what you considered in reaching
2 your opinions in this case; correct?

3 A. As you notice, I also considered the CE Mark
4 Analysis of the notified body. So the whole paragraph is
5 dealing with the asset acquisition diligence. So in order
6 for me to review that phase of the product, I had to
7 consider the activities in the context of that work.
8 That was what they were concerned with. The asset
9 acquisition diligence that they did, their own checklist
10 incorporated these various issues, and I'm stating that as
11 a part of my report.

12 So if you go to their checklist, they cite
13 certain things. I am summarizing what they were doing as
14 a part of their acquisition diligence.

15 Q. Okay. Here's where I think we may be having a
16 little bit of communication problem.

17 I asked you specifically about the 510(k)
18 application and clearance process. Your response to me
19 concerned the CE Mark Analysis by a notified body. That's
20 a separate issue. I am asking you a very simple question.

21 You considered the 510(k) application and
22 clearance process for the TVT-R in reaching the opinions
23 that you have put forth in your expert report; correct?

24 MR. DAVIS: Object to form.

1 THE WITNESS: Specific to this
2 paragraph, no. So in the example that you have cited, no,
3 I didn't -- that was not a part of it.

4 MR. DAVIS: Let her finish her answer.

5 THE WITNESS: Okay. The 510(k)
6 application, I have here parenthetically to explain that
7 during the asset acquisition diligence, Ethicon was asking
8 certain questions and trying to obtain certain
9 information, and parenthetically, they were familiar
10 already with the product because they had already done
11 these things. So in this paragraph, specifically, I'm
12 speaking of what they were doing during the asset
13 acquisition diligence, and I'm enumerating, basically,
14 what they were trying to do. I'm putting it in the
15 context of their activities. I don't need to look at the
16 510(k) to make this paragraph. I could have left that
17 parenthetic phrase out entirely.

18 BY MS. FITZPATRICK:

19 Q. Did you consider the 510(k) application and
20 clearance process in reaching your opinions in this case?
21 I've asked you that three times, now.

22 A. To the extent that the company had
23 accomplished that checklist, it is germane to this
24 paragraph, yes, ma'am.

1 Q. I'm not talking -- let me just make clear.

2 I'm not talking about a single paragraph on
3 page 17. I think that I've been very explicit in what
4 I've asked you. My question concerns what you considered
5 in reaching your opinions in this case.

6 Did you consider the 510(k) application and
7 clearance process for the TVT-R device when reaching your
8 opinions in this case?

9 A. No, mostly because in these cases, that 510(k)
10 had already been done with the exception of blue, and of
11 course, it's a part of my job to consider whether they
12 did what their obligations were or not. I didn't look at
13 the 510(k) in order to make any determinations because
14 there's nothing in the 510(k) that would have helped me
15 with this determination.

16 Q. Okay. So if you turn to page 12, you cite two
17 Ethicon TVT 510(k) applications; right?

18 A. Let me catch up with you. Are you talking
19 about the first bullet point, for example?

20 Q. The first bullet point, second bullet point,
21 third bullet point, the next paragraph on page 13.

22 A. I was looking at the FDA's guidance documents
23 for the content of the files that I was looking at, so I
24 was trying to make sure that the due diligence -- in my

1 due diligence review, that they had check-boxed all the
2 requirements for them. I do not mean to say that I made
3 my conclusions based on the content of the 510(k). I made
4 my conclusions that the performance testing that they did
5 to the standard, this standard that I'm citing, FDA
6 standard for surgical mesh. When I looked at the testing
7 records and the kind of information that went into that
8 submission, it was consistent with that FDA standard for
9 surgical mesh. This is how performance is judged when
10 you're looking at a standard of any type; did the data
11 conform to the standard of the realm.

12 Q. And the standard is what?

13 A. This guidance I mention here. There is no
14 international standard for surgical mesh performance other
15 than this guidance, and this guidance takes the form of a
16 standard because it sets down the requirements for
17 evaluation of the performance of any surgical mesh,
18 regardless of its application.

19 Q. Okay. So Ms. Duncan, I don't think this
20 is difficult, and I hope that I'm getting this right.

21 You looked at Ethicon's conduct here against
22 the standard, the FDA standard, which as you say is, "FDA
23 Guidance for the Preparation of a Premarket Notification
24 Application for a Surgical Mesh;" correct?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: But I did not make
3 my judgment based on the 510(k). I made my judgment
4 based on the information in the technical information.

5 BY MS. FITZPATRICK:

6 Q. Okay. So let's -- what I'm really trying to
7 understand is why I'm looking at two pages that must say
8 510(k) at least a dozen times, and I'm trying to
9 understand why we have a recitation of 510(k)s.

10 For example, "I have researched the FDA's
11 records and confirmed that Ethicon received a number of
12 510(k) clearances for the TVT product."

13 You wrote that; correct?

14 A. Yes.

15 Q. So you looked at and confirmed that Ethicon
16 had 510(k) clearances for its TVT products; correct?

17 A. As I said, I looked to confirm that they had
18 done their due diligence as a part of my due diligence.

19 Q. Okay. And part of the way that you determined
20 that they did their due diligence --

21 A. Part of it.

22 Q. -- is whether they received 510(k) clearances
23 from the FDA; correct?

24 A. That is a requirement, so I had to confirm

1 that as a part of my due diligence.

2 Q. And you reached the opinion that Ethicon
3 engaged in appropriate due diligence in connection with
4 the TVT-R product; correct?

5 A. I'm sorry, again? I confirmed due diligence
6 for the --

7 Q. In connection with the TVT-R product; correct?
8 That's your opinion?

9 A. Yeah, this -- just repeat the question, again.
10 I just -- the structure kind of lost me there. Say it
11 again.

12 MR. DAVIS: It really doesn't help to
13 keep making faces at the witness.

14 MS. FITZPATRICK: I'm just so perplexed.

15 MR. DAVIS: I think it's rude.

16 MS. FITZPATRICK: I mean, quite frankly,
17 I'm wondering if we need to do this a different day.

18 Maybe things --

19 BY MS. FITZPATRICK:

20 Q. You reached the opinion in your report that
21 Ethicon engaged in appropriate due diligence in connection
22 with the TVT-R product; correct?

23 A. The "in connection," you're very vague. I'm
24 trying to say my due diligence was different phases, and

1 for each of those phases, I found that the diligence
2 was proper and that the end result was adequate
3 performance as judged by the realm, standards of the
4 realm, and safety based on their behavior towards
5 complaints and hazard analysis and all of the things that
6 go into considering safety.

7 So when you just asked me due diligence, I
8 have to make sure I'm talking about the due diligence that
9 you're talking about.

10 Q. Okay. This is -- this is -- perhaps we do
11 need to get the Court on the phone to finish the
12 transcript.

13 I asked you to define "due diligence" for me.

14 A. I did.

15 Q. And I told you I was going to use your terms
16 so we didn't have this miscommunication issue that you
17 think we're having; okay?

18 I then asked you, very specifically, what I
19 think is a very simple question. You've reached the
20 opinion in your report that Ethicon engaged in appropriate
21 due diligence -- your term -- in connection with the TVT-R
22 product.

23 Isn't that what you say in your report, or did
24 I miss it?

1 A. In connection with. I'm just trying to
2 understand what you mean by "in connection with."

3 Q. As opposed to the TVT-O, as opposed to the
4 Prolift. We're talking -- you do understand we're here
5 talking about what Ethicon did with respect to the TVT-R
6 product? You understand that; right?

7 A. Now, you said it differently. You said --
8 so I can state myself that I believe they did their
9 due diligence for the product in each of the respective
10 phases that I reviewed for mechanical.

11 Q. And one of the things that you rely on to
12 reach that conclusion concerning due diligence is the fact
13 that Ethicon received a number of 510(k) clearances for
14 the TVT products?

15 A. It was only one of the things that I looked
16 at. I didn't rely on it exclusively.

17 Q. Okay. Perhaps you want to listen to my
18 question.

19 One of the things that you rely on to reach
20 that conclusion concerning due diligence is the fact that
21 Ethicon received a number of 510(k) clearances for the TVT
22 products?

23 A. The family of products. That was one of the
24 things I looked at.

1 Q. And that's what I asked you. So the answer is
2 "yes"?

3 A. Yes.

4 Q. And you go on in your report to say, "Despite
5 the impression created by the lay press, a 510(k)
6 submission is NOT" -- and you've got that capitalized,
7 -- "a 'shortcut to market.'"

8 What lay press are you referring to?

9 A. Any of the lay press. There's constantly -- I
10 live in an area where medical device companies are
11 concentrated, so the Star Tribune and the Pioneer Press
12 and any -- even the New York Times will often refer to a
13 510(k) as the shortcut process for FDA approval, and
14 that's the point I was trying to make.

15 Q. You -- do you believe that there's a
16 difference between the requirements for PMA versus 510(k)
17 clearance by the FDA?

18 A. It's not a belief; it's a fact.

19 Q. Okay. And you'll agree with me that the
20 510(k) submission takes a shorter period of time to get a
21 product to market; correct, than a PMA?

22 A. Not always.

23 Q. Okay. Give me an example of when a PMA took a
24 shorter period of time to get something to market than the

1 510(k) requirements.

2 A. I'm not sure I can recall something off the
3 top of my head like that, but there are a number of
4 products that have gotten on the market through a PMA
5 supplement that has taken, certainly, less than a year,
6 and I've been personally involved in 510(k)s that take
7 longer than a year.

8 Q. Okay. Tell me what those are.

9 A. As I said, I can't recall off the top of my
10 head these PMA supplements that have been short, nor
11 can -- would I be able to refer to 510(k)s that have
12 taken longer without divulging confidential information
13 of my clients'. I'm just explaining to you, I've been
14 personally involved in 510(k)s that have taken more than
15 a year and, I think, in fact, one of them was almost two
16 years, to be clear.

17 Q. Okay. Now, we started this whole discussion
18 by me asking what I thought was a simple question. And
19 the simple question is, you have relied on the federal
20 regulations and the 510(k) process as part or as one of
21 the bases for your conclusion that Ethicon acted
22 appropriately in bringing the TVT to market; correct?

23 A. I considered it as one. I didn't rely on it.

24 Q. Okay. Why do you spend two pages of probably

1 30 pages discussing the 510(k) process in detail if it's
2 not something that you relied on? Why did you choose
3 to spend this much paper doing that if it really has no
4 basis in your report?

5 Can I just scratch this whole section out?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: The question is can you
8 scratch it out?

9 BY MS. FITZPATRICK:

10 Q. Because it doesn't mean -- is it meaningless
11 in the connection with your report?

12 MR. DAVIS: Object to the form.

13 BY MS. FITZPATRICK:

14 Q. I'm trying to understand why.

15 A. It is not meaningless, but if you want to
16 scratch it out, feel free, because it would not make an
17 impact on my conclusions. If you chose to throw every
18 reference I've made to the 510(k) out of this report, my
19 conclusions would be the same.

20 Q. Okay. Well, about -- let me back up. About
21 10 minutes ago, you had a different answer, and I want to
22 make sure that I know which one is correct.

23 MR. DAVIS: Are you acknowledging that
24 you're repeating the same questions?

1 BY MS. FITZPATRICK:

2 Q. Ms. Duncan, you just told me that if you took
3 every reference to the 510(k) process out of this, it
4 would be the same report; correct? Is that what you just
5 said?

6 A. No, ma'am. I said if you took them out, my
7 conclusions would be the same.

8 Q. Okay. What you told me earlier is that -- I
9 asked you, "You're not able to issue this report without
10 considering the FDA regulations. Is that your testimony?"

11 And I asked you if it would be a different
12 report, and what you said is, "I can't say it without
13 attempting to do it. It wouldn't be what I normally do as
14 part of due diligence."

15 So would this report stay the same if you take
16 out references to the FDA regulations and 510(k) process,
17 or do you need to go back and do that and see what the
18 report would look like after that?

19 MR. DAVIS: I object to the suggestion
20 that those two answers are inconsistent with each
21 other.

22 THE WITNESS: And I'm sorry to ask you,
23 but please repeat the question because I was interrupted
24 in my train of thought. Please repeat the question.

1 BY MS. FITZPATRICK:

2 Q. I asked you, "You're not able to issue this
3 report without considering the FDA regulations. Is that
4 your testimony?"

5 Answer: "No, I could go back and revise the
6 report and leave out the FDA regulations, but it would be
7 less than a diligent job on my part because I have to be
8 present with respect to standards and regulations and best
9 practices that are current in each of these phases. So if
10 you want me to go back and revise the report, for example,
11 and take out just FDA regulations, it would be peculiar at
12 best."

13 Question: "Would it be a different report?"

14 Answer: "I can't say without attempting to do
15 it. It wouldn't be what I normally do as part of due
16 diligence."

17 Okay. That -- that's verbatim what you read
18 to me before.

19 A. And that's not inconsistent with what I said
20 later, because what I told you is that my conclusions
21 would be the same if you insisted on taking out any of the
22 510(k) references in my report.

23 You just reminded me that all of these people
24 that are listed on the front of this document are in the

1 United States, and now you would want me to remove the
2 regulations that apply to these people? I don't
3 understand why you would ask me to do that.

4 Q. I'm not asking you to do anything. I'm asking
5 if it would be possible to do that. I'm trying to
6 understand, Ms. Duncan, and I think -- quite frankly, I
7 thought it was a fairly simple concept.

8 You have relied on the FDA regulations to
9 reach your conclusions concerning the appropriateness of
10 Ethicon's conduct with respect to the TVT as set forth in
11 your report; correct?

12 MR. DAVIS: I object to the form. Go
13 ahead and answer.

14 THE WITNESS: Ma'am, yes, I have to
15 take exception to your word "relied." I've mentioned this
16 many times. You can ask me many times and I will not
17 agree to the term "rely." I did a more comprehensive task
18 than just looking at the FDA documentation. I looked at
19 worldwide documentation, so I take exception to your use
20 of the word "relied."

21 BY MS. FITZPATRICK:

22 Q. All right. We can parse words all day. Let
23 me make it easy.

24 You have considered the FDA regulations in

1 reaching your conclusions concerning the appropriateness
2 of Ethicon's conduct with respect to the TVT as set forth
3 in your report; correct?

4 A. I had to, yes.

5 Q. Okay. And you had to because you couldn't
6 reach the conclusions without considering.

7 Why did you have to do it, then?

8 MR. DAVIS: Object to the form.

9 BY MS. FITZPATRICK:

10 Q. Why did you have to do it?

11 MR. DAVIS: Asked and answered. You can
12 answer it again.

13 THE WITNESS: I will try to answer it
14 again.

15 As I told you, the due diligence process,
16 whether I'm looking at a potential acquisition for a
17 client or I'm looking at this specific task, the due
18 diligence process is a systematic process of looking at
19 the time frame we're talking about, the regulations and
20 standards and guidance documents and best practices at
21 that time frame, how they are reduced to practice into
22 procedures, and thirdly, how those procedures are
23 practiced by the personnel and the deliverables that come
24 from that work. All three of that pyramid must take place

1 in order to do a comprehensive due diligence, and I did my
2 best to do that throughout the effort that I put into this
3 report.

4 BY MS. FITZPATRICK:

5 Q. Is it -- I'm trying to understand what you're
6 saying.

7 Are you saying that you could not do a
8 comprehensive due diligence without considering the FDA
9 regulations in connection with this report?

10 A. It would be less than professional.

11 Q. Okay.

12 MR. DAVIS: At some point, let's take a
13 break, but you can finish this line.

14 MS. FITZPATRICK: Yeah, let me just
15 finish this; okay?

16 BY MS. FITZPATRICK:

17 Q. And because of your opinion on that, you
18 mentioned -- in assuming the three -- I don't know
19 where it is -- you said three of that pyramid.

20 One of the three things that is the
21 cornerstone or that you considered is compliance by
22 Ethicon with FDA regulations. It's one of the three?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: All regulations, whether

1 it's FDA or European, it's part of the comprehensive
2 review.

3 BY MS. FITZPATRICK:

4 Q. Okay. And that includes the FDA regulations;
5 right?

6 A. It has to include that and whatever
7 jurisdiction was appropriate at the time I'm looking at.

8 Q. Okay. And did you reach the conclusion, based
9 on your review of the documents, that Ethicon
10 appropriately complied with the requirements of the FDA
11 510(k) clearance process with respect to the TVT-R
12 mechanical device?

13 A. I did not do an extensive review of the
14 510(k). I did a cursory review for content and noticed
15 that the FDA had accepted it. I did not try to do due
16 diligence on the 510(k).

17 Q. Okay. Okay.

18 A. I've been drinking water.

19 Q. Oh, sure. Any time you need to take a break
20 like that, don't hesitate to ask me.

21 (Whereupon, a recess was taken from
22 2:34 p.m. to 2:45 p.m.)

23 BY MS. FITZPATRICK:

24 Q. Do you believe, Ms. Duncan, that the FDA's

1 review of the 510(k) submissions for the TVT products is
2 evidence that the TVT-R mechanical cut has met certain
3 scientific standards?

4 A. I would need you to qualify which scientific
5 standards you're speaking of.

6 Q. Okay. Well, maybe it's easier if you take out
7 a -- page 13 of your report.

8 A. Thank you.

9 Q. "These applications" --

10 A. Where are you, please?

11 Q. I'm in the fourth paragraph, third sentence.

12 "These applications follow strict submission
13 content examinations and must meet the FDA's
14 professional, scientific review standards."

15 Is that correct?

16 A. Okay. That's speaking of their internal
17 review standards, the way they practice their review.
18 They have review procedures, and they require certain
19 scientific evidence.

20 So what I'm speaking of there is the FDA's
21 review standards.

22 Q. Okay. So do you believe that the FDA's review
23 of the 510(k) submissions for the TVT-R product is
24 evidence that that product has met certain professional,

1 scientific review standards?

2 A. Do I believe that it's evidence that it's met
3 certain scientific review standards?

4 Q. Uh-huh.

5 A. It met the FDA's professional review
6 standards. In order to be clear, that's not -- I think
7 you need to understand "professional" and "scientific"
8 are not both modifying the word "review." So it's
9 professional standards and scientific standards that
10 they use when they are reviewing. So we're not -- we're
11 not speaking here in this sentence to any specific
12 scientific standards. That's not what I meant by that
13 sentence.

14 Q. What did you mean by "scientific review
15 standards"?

16 A. When FDA reviews, they have standards for
17 their review of a submission. They have professional
18 standards, and they have scientific standards when they
19 are conducting their review. It's their own internal
20 practices.

21 Q. Okay. So do you believe that the FDA's review
22 of the 510(k) submission for the TVT-R product is evidence
23 that that product has met these FDA professional,
24 scientific review standards?

1 A. I said the applications follow the strict
2 submission content examinations. I am not making a
3 judgment on the quality of the submission contents or
4 whether FDA did their job. My sentence is the
5 applications have to follow the strict submission content
6 examinations and their own internal standard.

7 So let me give you an example; okay? So when
8 we make a report to FDA, we have to submit both the
9 protocol and the report; we have to have an acceptance
10 criteria; we have to have statistical analysis of the
11 data; we have to describe the methodology for the testing
12 and sometimes even the test fixtures. Those are the
13 scientific review standards I'm speaking of. If they
14 don't see that quality as scientific work, they won't even
15 review the submission.

16 Q. So you don't have an opinion as to whether
17 Ethicon appropriately completed their 510(k) submission to
18 the FDA; correct?

19 A. When they were cleared by FDA, that meant that
20 they met FDA's expectations. I didn't judge whether or
21 not they did it well or did it poorly or -- I didn't
22 get in -- as I said previously, I did not do specific due
23 diligence on the submission, itself. I didn't judge the
24 content and FDA and the company. I just recognized that

1 they met FDA's requirement, and therefore, got the 510(k).
2 That's an upper-level review.

3 Q. Okay. Can you agree with me, Ms. Duncan, that
4 there are certain steps that a medical device manufacturer
5 must follow to responsibly develop a safe and effective
6 product?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: As I said previously, many
9 medical devices have been very successfully designed
10 without following certain steps.

11 BY MS. FITZPATRICK:

12 Q. But there's a reason this process exists.
13 You agree; right?

14 A. Certainly. I was part of helping to
15 accomplish that.

16 Q. Okay. And medical device manufacturers are
17 not the wild west. There's a certain way and certain
18 steps that a medical device manufacturer should follow to
19 ensure that they are making the safest, most effective
20 product feasible; right?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: I have to answer
23 that in the context of today. There are requirements
24 today, there were requirements yesterday, there were

1 requirements a year ago. And when we look at the certain
2 steps, as you've called them, I have to be in the context
3 of what are the requirements in that time frame. I can't
4 make a generalization, as you would hope.

5 BY MS. FITZPATRICK:

6 Q. Okay. Not helping. Let me ask you,
7 regardless of the time frame, it's important that a
8 medical device manufacturer follow the requirements that
9 are in effect at that time; correct?

10 A. If you're speaking of regulatory requirements,
11 obviously.

12 Q. I'm not speaking about regulatory
13 requirements.

14 Do you believe that a medical device
15 manufacturer has an ethical obligation to create the
16 safest product that it can?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: That's essentially the
19 Code of Ethics of most of the medical device manufacturers
20 I work with.

21 BY MS. FITZPATRICK:

22 Q. Do you agree with it or not?

23 A. Yes, I agree with it.

24 Q. Okay. And you will agree with me that to

1 fulfill that ethical obligation, a medical device
2 manufacturer needs to follow a process to establish the
3 safety and feasibility of a product before it goes on the
4 market; correct?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Please forgive me, but
7 your questions are rather tangled. If you can break it
8 down, I'd be happy to try to answer it.

9 MS. FITZPATRICK: Could you read the
10 tangled question back?

11 (The record was read back.)

12 THE WITNESS: "Needs to follow a
13 process." Read from that point. "Needs to follow a
14 process."

15 (The record was read back.)

16 THE WITNESS: Okay. I guess what
17 stumbled me here was you put "feasibility" at the end of
18 the question, so if we took "feasibility" out of that
19 question, I can agree with you in principle, because you
20 have it backwards, basically.

21 BY MS. FITZPATRICK:

22 Q. You don't think that -- well, let me break it
23 down to two if that makes you happy.

24 Will you agree with me that to fulfill that

1 ethical obligation, a medical device manufacturer needs to
2 follow a process to establish the safety of a product
3 before it goes on the market?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: "A process" is rather
6 vague, but in general, they follow processes.

7 BY MS. FITZPATRICK:

8 Q. Okay. Now, you agree with me that, ethically,
9 the aim of a medical device manufacturer is not just to
10 create a product that is safe enough. It must be the
11 safest feasible under the circumstances; is that correct?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: We don't always know that
14 answer, so when you say, "Is that correct?" again, I have
15 to look at time frame because we get new information as
16 the product is used and even in different markets for
17 different applications. So when you write a broad -- you
18 say a broad statement like that, you're asking me to
19 assume that we always know everything we need to know,
20 and it's not true.

21 BY MS. FITZPATRICK:

22 Q. Is it difficult for you to agree with me that
23 a medical device manufacturer should create the safest
24 product feasible under the circumstances? Is that

1 difficult to agree with?

2 MR. DAVIS: Object to form.

3 THE WITNESS: "Under the circumstances"

4 is the vague part, but with respect to the -- to that, I

5 think it's a generally agreeable statement that we need

6 to make them as safe as feasible, but I don't know the

7 circumstances you're speaking of.

8 BY MS. FITZPATRICK:

9 Q. Okay. Let me redraft my question again for
10 you.

11 Should a medical device manufacturer create
12 the safest product feasible?

13 A. If they choose to make it, yes, they should.

14 Q. And in doing that, a medical device
15 manufacturer has to take into account everything that
16 could go wrong with the product; correct?

17 A. In my professional world, I have to be
18 precise. So "everything that could go wrong"?

19 Q. Uh-huh.

20 A. I believe that's quite imprecise, and I mean,
21 an alien could get the product and misuse it, and believe
22 me, I've sat in on hazard analysis where people will even
23 bring up aliens.

24 So there are limitations to our ability to

1 make the safest product, and "could go wrong" is a very
2 broad term. We have to be specific when we develop our
3 hazard analysis and risk assessment.

4 Q. So you can't just agree with me that a medical
5 device manufacturer must take into account everything that
6 can go wrong with the product when designing it? You
7 can't agree with that statement?

8 A. You dropped your voice at the end.

9 Q. So you can't just agree with me that a medical
10 device manufacturer must take into account everything that
11 can go wrong with the product when designing it?

12 A. "Everything that can go wrong," I -- we would
13 never make the product if we made -- if we followed that
14 concept that you just espoused, "everything that can go
15 wrong." We can't make a product for everything that can
16 go wrong. We'd never have one.

17 Q. Let me repeat the question again. So we'll
18 try this a third time.

19 Can you agree with me that a medical device
20 manufacturer must take into account everything that can go
21 wrong with a product when designing it?

22 MR. DAVIS: Object; asked and answered.

23 THE WITNESS: My same answer. We cannot
24 take everything into account because, A, we may not know

1 everything, and two, we might not ever make one.

2 BY MS. FITZPATRICK:

3 Q. Okay. You certainly can agree with me that a
4 medical device manufacturer must take into account known
5 risks when designing a product; correct?

6 A. Known risks, yes, ma'am.

7 Q. And you can agree with me that a medical
8 device manufacturer must take into account all foreseeable
9 risks associated with the product?

10 A. "All" is a big word, but "foreseeable," I
11 would agree with.

12 Q. I need to get the full question out, so --

13 A. I'm sorry.

14 Q. You can agree with me that a medical device
15 manufacturer must take into account all foreseeable risks
16 associated with the product when designing it; correct?

17 A. All foreseeable risks, I would agree with
18 that.

19 Q. Okay. And you agree with me that a medical
20 device manufacturer must take into account all potential
21 hazards associated with a product when designing it;
22 correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: There's an issue with the

1 word "all possible hazards" because all possible hazards
2 may not be defined. We have to understand the potential
3 to do harm, and that's not always known at the time of the
4 design and development.

5 BY MS. FITZPATRICK:

6 Q. Okay. Do you agree with me that a medical
7 device manufacturer must take into account its past
8 experiences with other medical devices when developing a
9 new medical device?

10 A. Not only their own past experiences, but the
11 experiences of others in similar product areas.

12 Q. Okay. Now, a responsible medical device
13 manufacturer should never assume that their product is
14 safe without verification or validation of the design;
15 correct?

16 MR. DAVIS: Object to the form.

17 THE WITNESS: I don't know of anyone who
18 assumes safety.

19 BY MS. FITZPATRICK:

20 Q. That would be a bad thing to do; wouldn't it?

21 A. Assuming safety?

22 Q. Yes.

23 A. I think there are some considerations for
24 modifications to products and different applications where

1 we can build from past experience, as you say, but that's
2 not necessarily an assumption. That's developing from
3 past experiences.

4 Q. You'll agree with me that a medical device
5 manufacturer should err on the side of caution when
6 investigating potential safety concerns and hazards
7 associated with their products; correct?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: Err on the side of
10 caution, that's not a phrase we typically use. We don't
11 err on the side of caution. We write precautions and
12 cautions and warnings, and so we don't err on the side of
13 caution.

14 BY MS. FITZPATRICK:

15 Q. Have you ever heard that phrase before?

16 A. It's not something we use in my field of
17 expertise.

18 Q. Have you ever heard that phrase before?

19 A. Certainly.

20 Q. And what do you understand it to mean?

21 A. Again, in the medical device industry, we
22 don't err on the side of caution.

23 Q. Okay.

24 A. We don't deliberately err anywhere.

1 Q. Okay. Now, I want to go through a couple of
2 issues to make sure that we're on the same page as we
3 discuss these concepts going forward.

4 Do you understand that the term "concept"
5 means coming up with the idea of a product? You come up
6 with the concept of a potential medical device that can be
7 created; correct?

8 A. Sorry to do this again, but this has a
9 specific meaning in design and development -- design,
10 control and review. So a concept phase or a concept stage
11 has specific connotations.

12 Q. Okay. Tell me what the concept stage is.

13 A. Typically, we're taking it -- we're taking a
14 look at our -- the conceptual context would be is
15 there a market? Is there a need? Is there technological
16 capability? Do we generally understand what is needed
17 about the product? But these are all very general
18 contexts. We -- it's an exploratory process, the concept
19 phase.

20 Q. Okay. It sounds to me like it's coming up
21 with the idea for a product, but we can differ on that.

22 What does feasibility mean?

23 A. Typically, when I see feasibility, what we're
24 really looking at, then, is as we've moved from concept,

1 have a conceptual perspective of what the product is
2 going to do, I now need to understand whether or not there
3 is technology to support it. Can I make a prototype? Can
4 I make it in 3D form? Is it -- literally, is it feasible
5 for me to even make the product?

6 Q. Thank you. Do you agree with me that the next
7 step would be to actually design a prototype of the
8 product?

9 MR. DAVIS: Object to form.

10 THE WITNESS: Sometimes it's done in the
11 feasibility stage. Sometimes it's even done in the
12 concept stage. There's no rigid rule about when you make
13 the prototype.

14 BY MS. FITZPATRICK:

15 Q. But you have to design it; correct? Someone,
16 somewhere, has to design the product; right?

17 A. Ma'am, I'm a mechanical engineer, so when I
18 think in terms of designing it, I'm usually talking in
19 terms of drawing it. And so there are a lot of products
20 that are never drawn or designed in that vernacular. So
21 designing is the entire process. It's not one event.
22 Somebody just doesn't sit down and say, "Oh, I designed
23 it."

24 Q. And any time -- let's use this pen. Bic came

1 up with the concept of their Velocity Gel 0.7 pen.

2 Let's just assume that for the purposes of
3 this; correct?

4 A. If you choose to.

5 Q. How did this exist if someone didn't come up
6 with the idea?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: You said "someone."

9 Often, it's a team. Often, it's a modification of an
10 existing product. That product's been around for a long
11 time. I couldn't tell you how it came about.

12 BY MS. FITZPATRICK:

13 Q. This particular pen?

14 A. Uh-huh.

15 Q. Someone or someones came up with the concept
16 of this pen.

17 A. I can take that on faith.

18 Q. Okay. And to get from the concept to what it
19 is I hold in my hand, someone actually, at some point, had
20 to build a pen; right?

21 A. Yes.

22 Q. And that first pen that was built is the first
23 prototype of this pen; correct?

24 A. Ma'am, not always. I'm sorry to say that.

1 Q. Okay.

2 A. That isn't always the way it works.

3 Q. Tell me why not.

4 A. Because if Bic already knew a lot about pens,
5 they might have gone directly into production. They may
6 have never made a prototype.

7 Q. What would you prefer to talk about?

8 MR. DAVIS: Object to the form. How can
9 she answer that question?

10 MS. FITZPATRICK: Because it's such a
11 simple concept, but -- and it's a little frightening that
12 you don't understand it, but okay.

13 BY MS. FITZPATRICK:

14 Q. Included in the design is, you need to do a
15 risk analysis. So let's just assume this is the very
16 first one of these and this is the very first prototype;
17 okay? We didn't go directly to market. We're making a
18 new product -- this is it -- and Bic makes its first
19 prototype of this pen; okay? Let's just assume that.

20 Bic should then test this pen to make sure it
21 does what it's supposed to do, that it's effective;
22 correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I'm sorry, I don't know

1 what you mean; should they test it? Does it write? Is
2 that what you're asking?

3 BY MS. FITZPATRICK:

4 Q. Sure. Does it do what it's supposed to do?
5 Isn't that what I said? Yeah, does what it's supposed to.
6 And you know a pen is supposed to write, so --

7 A. I presume they did, but I don't understand
8 the --

9 Q. They should test it to make sure that it
10 actually writes; correct?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: Again, "should" is a big
13 word in my world. "Should" is a requirement. I don't
14 know if Bic has that requirement. I would think that, to
15 save money from doing it poorly, they would probably test
16 it somewhere along the line, but you're asking me to
17 conjecture, and "should" means a requirement.

18 I'm a regulatory professional, and I will use
19 the term of art in my world, and "should" is a
20 requirement. So I can't say what Bic should or should not
21 do.

22 BY MS. FITZPATRICK:

23 Q. How much have you been paid by Ethicon here?

24 A. I think you can call back the record, I --

1 Q. About \$60,000?

2 A. Probably.

3 Q. So Ethicon has paid you \$60,000 and you still
4 have no idea what we're talking about here?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Yes, I object to the
7 form. I didn't say I didn't have any idea of what you
8 are talking about. I said I don't know what Bic has to
9 do.

10 BY MS. FITZPATRICK:

11 Q. Okay. Does Ethicon have an obligation to do a
12 risk analysis on the TVT-R?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: To -- today, they do a
15 risk analysis on a periodic basis as a part of the risk
16 management. And so, therefore, I can say yes, they would
17 need to be doing that.

18 BY MS. FITZPATRICK:

19 Q. Okay. And Ethicon had an obligation to do a
20 risk analysis on the TVT-R since 1998; correct?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Actually, in 1998, their
23 obligation to do one, it would not reside at Ethicon.
24 It would reside at Medscand, and they did.

1 BY MS. FITZPATRICK:

2 Q. After Ethicon acquired the TVT-R, they had a
3 duty to continue to monitor the product that they were
4 marketing for safety; correct?

5 A. That's correct.

6 Q. So from the time that Ethicon acquired the
7 TVT-R, it was under a continuing obligation to monitor the
8 TVT-R mechanical device for safety considerations.

9 A. Excuse me, I wouldn't characterize it as a
10 mechanical device, if you mean a mechanical cut.

11 Q. Okay. So from the time that Ethicon acquired
12 the TVT-R, it was under a continuing obligation to monitor
13 the TVT-R mechanically-cut device for safety
14 considerations; correct?

15 A. That's correct.

16 Q. And Ethicon was not permitted to simply rely
17 on what Medscand had done and turn a blind eye to any new
18 safety considerations that came up post-1998; was it?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I don't understand the
21 blind eye that you're referring to. If you --

22 BY MS. FITZPATRICK:

23 Q. Have you ever heard the term "turn a blind
24 eye"?

1 MR. DAVIS: Let her finish her answer.

2 THE WITNESS: If you would like to break
3 the question down again, it was lengthy and I didn't
4 understand what you were driving at. So "blind eye," I
5 don't know when you mean a "blind eye." Whose blind eye,
6 and when and where and what?

7 So if you want to rephrase the question, I'll
8 try to answer it.

9 MS. FITZPATRICK: Can you read the
10 three-line, convoluted, confusing question back to
11 Ms. Duncan?

12 (The record was read back.)

13 THE WITNESS: In my due diligence, I
14 never saw a situation where Ethicon, as you put it, turned
15 a blind eye to any known questions of safety -- not only
16 not safety, but questions of safety. My due diligence
17 showed -- for me, the records I looked at, showed that
18 they were diligent in their review of safety from the time
19 period that they began to market the product, and that
20 was, I believe -- I know the acquisition was November '97,
21 and so I -- I'm sorry, I'm blanking on the actual date
22 when they put the product into the market.

23 BY MS. FITZPATRICK:

24 Q. I'm going to ask you to listen to my question

1 and answer my question. I didn't ask you whether Ethicon
2 did turn a blind eye. I asked you whether Ethicon was
3 permitted to turn a blind eye to any new safety
4 considerations that arose after 1998?

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Permission from whom?

7 BY MS. FITZPATRICK:

8 Q. Any kind of standards. You got a lot of
9 requirements in here.

10 You really don't know what we're talking
11 about?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I didn't say I didn't
14 understand what you were talking about. I'm trying to
15 understand your sentence. So were they permitted?

16 So regulatory agencies that were in place at
17 the time would have not given any manufacturer permission
18 to turn a blind eye. Is that -- are we getting close?

19 BY MS. FITZPATRICK:

20 Q. That's exactly what I asked.

21 A. Okay.

22 Q. Okay. And do you know what a living document
23 is?

24 A. I would assume that you're speaking of a

1 document that is revised and changed according to the
2 context with respect to standards and regulations.

3 Q. What's an FMEA?

4 A. A failure mode effects analysis.

5 Q. And what's a risk assessment?

6 A. A risk assessment, typically, goes beyond a
7 simple FMEA.

8 Q. Tell me how. Let me just do this.

9 What's the difference between an FMEA and a
10 risk assessment?

11 A. Well, actually, some FMEAs include a risk
12 assessment. Basically, a failure modes effects analysis,
13 the analysis part of it is where we take the failure
14 mode and its effect and try to score it, and some
15 individuals consider that relational assessment of
16 the severity, frequency and detectability a form of
17 assessment. Other people believe that assessment takes
18 place in addition to an FMEA.

19 Q. What is a design FMEA?

20 A. That's, typically, where we'll take the input
21 requirements at an early stage in the design and
22 development and attempt to project or hypothetically
23 define a potential hazard based on the failure to meet
24 that input requirement. Sometimes, the information is

1 based on prior products, prior literature, but in the
2 design phase, we may not be fully knowledgeable about what
3 the hazards are associated with a specific product we're
4 working on.

5 Q. Okay. You would agree with me that any known
6 hazard should be included in a dFMEA; correct?

7 A. We certainly try to incorporate known hazards.

8 Q. And the dFMEA is actually a document;
9 correct -- something that you can look at to see what a
10 company considered as potential hazard; right?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: A dFMEA, is that what you
13 asked?

14 BY MS. FITZPATRICK:

15 Q. Yep.

16 A. All FMEAs eventually become a type of form of
17 a document, yes.

18 Q. Okay. And that document should include any
19 known hazard or known potential hazard; correct?

20 A. As I said previously, we try to define the
21 known hazards. If they're known, we try to include
22 them, certainly.

23 Q. And it should also include the foreseeable
24 hazards associated with the use of the product; correct?

1 A. We try and base that on literature and
2 knowledge from other products.

3 Q. And that dFMEA is a living document, meaning
4 that as a company acquires knowledge of additional or new
5 hazards, it should incorporate them into the dFMEA on an
6 ongoing basis; right?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: I can tell you that the
9 practice in the industry is frequently to consider that
10 the design FMEA is only active -- is only an active
11 document during the design and development phase, and once
12 the product is transferred to manufacturing in the design
13 transfer phase, that many companies will consider that
14 document as a part of the design history file, would only
15 go back to that document if they intend to make
16 significant changes to the design. So it's not really a
17 perpetual document as you're inferring.

18 BY MS. FITZPATRICK:

19 Q. Okay. Would you agree with me that one of the
20 purposes of the dFMEA is to minimize the failure effects
21 of a particular design?

22 A. We -- it helps us define the failure modes,
23 and it helps us to evaluate counter-measures.

24 Q. And by "counter-measures," you're talking

1 about either designing out the risk, if that's feasible;
2 correct?

3 A. That may be one method.

4 Q. And another method is to, if you can't
5 completely design out the risk, you work to minimize the
6 risk that's in the product; correct?

7 A. That's typically what will occur.

8 Q. Okay. And the third is if you can't design it
9 out or minimize it, is to include that hazard of risk on
10 an instruction for use or a warning to the consumer;
11 correct?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: In a broader sense, the
14 residual risks are often incorporated in communications,
15 and that takes the form of labeling, and labeling includes
16 an IFE, but that's not the only way we communicate.

17 BY MS. FITZPATRICK:

18 Q. Okay. But you're talking about communicating,
19 in whatever form, a risk to, in this case, it would be the
20 physician; correct? So if a physician understands that
21 there are certain risks or hazards inherent in the
22 product?

23 A. You've used a lot of terms there, so a hazard
24 has the potential to do harm, and when we assess risk,

1 we're also looking at severity. So we are in the review
2 of the mitigation measures we take and the communications
3 we make, we consider not only the potential to do harm,
4 the hazard, but we also consider the severity and
5 detectability, and based on all three of those judgments
6 and the testing, we come to a conclusion of the best way
7 to mitigate the hazards.

8 Q. Again, we're talking about through the
9 communication --

10 A. That's one way. Sometimes it's testing. To
11 understand the limits of the product, if we can test
12 on the bench, we can test in the animals, and we can test
13 in a clinical trial, and in each of these sequential
14 validations, if that's what's required -- sometimes it's
15 only bench testing -- as this body of knowledge is formed,
16 we continue to go back into that hazard analysis and make
17 sure that we haven't gained different information and try
18 to make the best comprehensive decisions on the hazards
19 we've identified.

20 Q. Okay.

21 A. So it may take iterations. It's not just one
22 sit-down and one and done.

23 Q. Okay, agreed. So you start, you try to
24 mitigate the risks, the harms in whatever way you can.

1 A. Uh-huh.

2 Q. You test it again. If it's still at an
3 unacceptable range or something you're concerned about,
4 you can go back to the design process.

5 You try to come up with modifications to the
6 design that will minimize the risks to patients; correct?

7 A. It's important to realize that a failure modes
8 effects analysis does not necessarily always mean that a
9 failure to meet the input requirement creates a harm or a
10 hazard to the patient. So a component or a part may
11 fail at a defined time without necessarily engendering
12 a harm to the patient. So all of that is taken into
13 context.

14 Q. Okay. But you'll agree with me that the
15 purpose of the dFMEA is to allow a company to -- a medical
16 device manufacturer, to consider the potential failure
17 modes and attempt to make modifications to the design of
18 the product, if necessary, to minimize any failure modes
19 and risks of harm. That's why you do it?

20 MR. DAVIS: Object to form.

21 THE WITNESS: As a part of that
22 assessment phase that we were speaking of.

23 BY MS. FITZPATRICK:

24 Q. Uh-huh.

1 A. We assess which of the failure modes may
2 need to be addressed, and this is a -- if you will,
3 hierarchical process. So you certainly attempt to put
4 your focus on any failure that would have a high severity
5 and a high potential, first. So it's a resource
6 management tool, as well.

7 Q. So to use your analogy from earlier, someone
8 may come up at a meeting with an idea that aliens come
9 from Mars, and you're not going to spend a whole lot of
10 time redesigning the product to minimize that risk because
11 it's such a minor risk; correct?

12 A. The potential is low.

13 Q. The potential is extraordinarily low; correct?

14 A. (Witness nodding head.)

15 Q. Okay. But you'll agree that, as a company
16 identifies potential failure modes that have severity or
17 have a high probability of occurring or are very difficult
18 to detect, that a company will take those into account and
19 see if there's a modification to the design of the product
20 that would minimize those potential failure modes. That's
21 generally how it works. It's the concept behind it.

22 MR. DAVIS: Object to the form.

23 THE WITNESS: Again, this design FMEA or
24 whatever other method -- there are other methods besides

1 design FMEA for assessing any product, whether it's new or
2 a modification. This is only one tool.

3 So as going through design phase, a design
4 FMEA is a typical tool but not the only tool.

5 BY MS. FITZPATRICK:

6 Q. Okay. I'm going to ask you to answer my
7 question.

8 A. I'm sorry, I got lost in my answer.

9 Q. Yeah. You'll agree with me that as the
10 company identifies potential failure modes with severity
11 or a high probability of occurring or are difficult to
12 detect, a medical device manufacturer should take those
13 into account to see if there's a modification to the
14 design of the product that would minimize those potential
15 failure modes.

16 That's generally how the process works; right?

17 MR. DAVIS: Object to the form.

18 THE WITNESS: Only within the
19 design and development context. When the information
20 occurs for a mature product, a product already on the
21 market, going to the design FMEA is not the most expedient
22 path for addressing the information that's been
23 identified.

24

1 BY MS. FITZPATRICK:

2 Q. Okay. Let's make this easy.

3 Why do companies do design FMEA? What's the
4 purpose?

5 A. It's one of many tools.

6 Q. So accomplish what?

7 A. As I mentioned, one of the benefits is it
8 helps to define the verification and validation testing
9 that needs to be done for a product. We -- as I said,
10 it's hierarchical, so oftentimes, as a part of the project
11 plan, the design plan where we have to do verification and
12 validation, we would design the verification and
13 validation protocols with the information we have gained
14 from the risk analysis document.

15 Q. Okay. I think I'm, perhaps, asking an easier
16 question than you're hearing.

17 Is one of the reasons why companies do design
18 FMEAs to attempt to minimize the potential risk to
19 patients of that medical device?

20 A. During the design phase, that's one of the
21 tools.

22 Q. Okay. That's one of the reasons that a
23 company does a dFMEA; right?

24 A. As I said, in a design phase, it's one of the

1 tools. There are many tools, including a usability FMEA.

2 Q. Okay. And a design FMEA can provide a medical
3 device manufacturer with information and inputs it needs
4 to go back and look at whether modifications to the
5 original design of the product are necessary to protect
6 patient safety; correct?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: I believe you have it
9 backwards a little bit. The inputs are already known when
10 we're doing a design FMEA. So the design FMEA, itself, is
11 not an input. The output of a design FMEA may be useful
12 in establishing the verification and validation planning,
13 which would include bench testing, animal testing. It can
14 also be valuable for helping to define labeling, as an
15 example.

16 BY MS. FITZPATRICK:

17 Q. But see, I'm asking you something else, and so
18 I'm not sure where you're going, here.

19 Let me try again.

20 A dFMEA can provide a medical device
21 manufacturer with information it needs to go back and look
22 at whether modifications to the original design of the
23 product are necessary to protect patient safety; correct?

24 A. No.

1 MR. DAVIS: Wait a second. Object to
2 form and asked and answered.

3 BY MS. FITZPATRICK:

4 Q. Okay. So a dFMEA doesn't provide medical
5 device manufacturers with any information to allow it to
6 go back and look at the original design of a product and
7 see whether modifications are necessary?

8 A. You changed the question.

9 Q. No, I really didn't, but why don't you just
10 tell me what you mean?

11 A. You said "any," and the original question
12 was not the same. So if you'd like to ask it again,
13 I'll try to answer it.

14 Q. Sure. Absolutely.

15 A dFMEA can provide a medical device
16 manufacturer with the information it needs to go back and
17 look at whether modifications to the original design of a
18 product are necessary to protect patient safety?

19 MR. DAVIS: Object to the form and asked
20 and answered.

21 THE WITNESS: To go back and look. So
22 we have a design FMEA, and as I explained previously, the
23 design FMEA is focused to the design process, and so for
24 you to say that it gives them tools for going back, going

1 back to what? That's where you lose me. To go back to
2 the --

3 BY MS. FITZPATRICK:

4 Q. The original design of the product. You
5 design -- this is remarkably concerning.

6 You design a prototype of a new product;
7 correct?

8 A. Uh-huh.

9 Q. The company can then do a dFMEA to look at all
10 of the potential known and foreseeable failure modes for
11 that prototype, that original design for the product;
12 correct?

13 A. I'm sorry, I cannot answer the question you've
14 asked because you're oversimplifying, and you have it
15 backwards.

16 Q. Okay.

17 A. I can actually do a design FMEA and never have
18 a prototype.

19 Q. You have to have a design before you do a
20 design FMEA; right? I can't possibly have that backwards.

21 A. Excuse me, ma'am, but if -- you have to have
22 input requirements to the design. I know it's not your
23 field, but when we do a design FMEA, we're doing it
24 based on the input requirements. The input requirements

1 are not necessarily the design; they're the inputs into
2 the design. I may not even have a drawing or a form. I
3 may not have a prototype or even something made out of
4 straw at the time I'm doing a design FMEA because I'm
5 basing my design FMEA on input requirements.

6 And if I may, examples of input requirements
7 are the prevailing regulations of the day, the prevailing
8 standards of the day, the expectations of the customer of
9 the day, and the intended use and indication for use of
10 the product at the time we're doing the design input
11 requirement. There are multiple standards like software
12 standards, hardware standards, biomaterial standards. We
13 have to incorporate all of that into the input
14 requirements. We take the input requirements and build a
15 hazard analysis document. I know it sounds bizarre, but
16 it can be totally independent of having a drawing or a
17 prototype.

18 Q. Okay. So you, in your job, can actually
19 figure out how a product might fail before you even know
20 what that product is and before you even know what the
21 design of that product is. That's how you do it?

22 MR. DAVIS: Object to the form.

23 THE WITNESS: You're taking it out of
24 context, what I said. I said you can take input

1 requirements or that product and develop a hazard analysis
2 surrounding that input requirements, and you may or may
3 not have a prototype, you may or may not have a final
4 design. I can have sketches. I can do an input
5 requirement. In fact, I have done input requirement
6 documents before anybody's ever put pen to paper. I can
7 do that in parallel with the design process of the design
8 you talk about like drawing it or making it. I can do
9 that in parallel and -- repeatedly throughout the whole
10 process, as inputs change, as I learn new information
11 about the product.

12 BY MS. FITZPATRICK:

13 Q. But the design FMEA looks at a failure mode,
14 the potential failure modes of a medical device; correct?

15 A. A design FMEA specifically takes each input
16 requirement and propositions what could be the failure
17 mode if I fail to meet the input requirement that I've
18 established.

19 So first I draft the input requirements
20 document. Again, they're all in the whole, make that
21 document, and then, in parallel to other people doing
22 their tasks, I can start my design FMEA because I'm taking
23 the input requirements and I'm proposing the potential
24 failure modes based on the failure to meet that input

1 requirement. It's very structured in a design FMEA.

2 That's the way it's supposed to be done.

3 Q. It is very structured; isn't it?

4 A. Very structured.

5 Q. And there's a certain way that it's supposed
6 to be done; correct?

7 A. It's done many different ways. I've seen
8 dozens and dozens of different FMEA documents in every
9 company I work with.

10 Q. Is it structured or not?

11 A. As I said, every company will structure their
12 own FMEA format. There's no one FMEA format that fits all
13 people.

14 Q. Okay. So it's structured but done in lots of
15 different ways.

16 Is that what you're telling me?

17 A. It's -- it -- there is a specific style that
18 you will find in common. There are columns, there are
19 rows, there are headers. Oftentimes, there's scoring.
20 Some people don't put in detectability, as an example.
21 Some companies put in a second phase of the scoring where
22 they evaluate the risk and potential after they have done
23 mitigation. I've seen some FMEAs that are three feet long
24 and multiple pages. I've seen some FMEAs that fit on

1 8-and-a-half-by-11.

2 So there is no one size that fits all
3 products, but typically, a company will establish within
4 it, for itself, its preferred style of procedure that
5 would mean how do you do an FMEA in our shop. That's
6 typical.

7 Q. So Ethicon can do whatever it wants in coming
8 up with a design FMEA? It's whatever way it wants to do
9 it; is that right? You follow procedure?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Excuse me. I'm sorry,
12 you're saying they can do whatever they want.

13 BY MS. FITZPATRICK:

14 Q. Yes. "A company will establish within it, for
15 itself, its preferred style of procedure. That will mean
16 how you -- how do you do an FMEA in our shop."

17 So I'm asking you, did Ethicon establish
18 within it, for itself, a preferred style of procedure that
19 meant how it did an FMEA in its shop?

20 A. In multiple times, in multiple locations, yes,
21 they had various formats depending on the location and the
22 time.

23 Q. Okay.

24 A. But they typically were, as I said, columns

1 and rows and typically looked at the potential failure
2 mode of the input requirement. But again, the input can
3 be the user input, the design input or the process.
4 There's the three typical forms of FMEA.

5 Q. Okay. So I was just going to ask you.
6 There's a process FMEA; correct?

7 A. Uh-huh.

8 Q. There's an application FMEA; correct?

9 A. Some people call that a usability FMEA.
10 That's not a hard term of art.

11 Q. Okay. If a company knows of the risk or
12 potential failure mode and doesn't include it in it's
13 FMEA, is the FMEA incomplete?

14 A. As I mentioned before, a potential failure
15 mode does not necessarily mean there's a risk associated
16 with it.

17 Q. If a company knows of a potential failure mode
18 that is associated with a risk to a patient and doesn't
19 include it in the FMEA, is the FMEA incomplete?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: If they know of it. As I
22 said, there are various layers of FMEAs, and so a
23 potential failure mode may be captured in a particular
24 type of FMEA but not in another.

1 BY MS. FITZPATRICK:

2 Q. It's got to be in one of them; right?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: Again, if they have
5 discovered this information after the product has already
6 reached the market, they are often going to assess that
7 risk outside of a FMEA document. They may not go all the
8 way back to a previous signed-off design level FMEA in
9 order to treat that particular risk that they've
10 identified.

11 MR. DAVIS: In about five minutes, let's
12 do another break.

13 BY MS. FITZPATRICK:

14 Q. Let me try this again with you because you
15 seem to want to be talking to me about the exception
16 rather than the rule. I'm talking the rule.

17 A. I'm a trainer.

18 Q. Okay. You'll agree with me that before
19 marketing, if a company knows of a potential failure mode
20 that's associated with a risk and does not include that in
21 it's FMEA -- again, before marketing -- that FMEA is
22 incomplete; correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: I can't say 100 percent of

1 the time it's incomplete because you have to go back to
2 the input requirements to do the FMEA. So the first thing
3 they would need to do is go back and assess why their
4 input requirements hadn't caught that potential hazard.

5 BY MS. FITZPATRICK:

6 Q. Let me give you -- let me give you a
7 hypothetical. I'm not going to give you a hypothetical.
8 I'm going to give you an actual.

9 A. Can we do that after a break?

10 Q. Sure. Let me ask you just a couple questions.
11 You said you can't say 100 percent of the time
12 it's incomplete.

13 Would you agree with me that the majority of
14 the time that would be considered incomplete?

15 MR. DAVIS: Object to form.

16 THE WITNESS: Again, the incompleteness
17 is a perspective on the input requirements. What we
18 would do if we found out about a potential hazard that
19 had not been captured on any one of the FMEAs, is we
20 would go back, first, to question our input requirements
21 and assess whether or not we were capturing the proper
22 input requirements, because an FMEA, you don't just plop a
23 hazard down into an FMEA. I told you, it's a process of
24 going from input requirements through failure modes,

1 through effects, scoring severity, scoring potential.

2 So when someone comes up with a risk that we
3 haven't captured in a document, we have to go all the
4 way back and assess how did we not capture an input
5 requirement that would have led to this newly-discovered
6 risk.

7 BY MS. FITZPATRICK:

8 Q. But see, you changed what I asked you. I'm
9 not asking you about a newly-discovered risk
10 postmarketing.

11 A. I didn't say you were.

12 Q. You just said the input requirement that would
13 have led to this newly-discovered risk. I'm not talking
14 about a newly-discovered risk. That was your part. I'm
15 looking at your answer right there. So let me try
16 again.

17 If a company has actual knowledge of a failure
18 mode associated with a product that can cause a risk of
19 harm to a patient and does not include that on its FMEA,
20 you will agree with me that, barring -- you will agree
21 with me that the majority of the time, that FMEA is
22 incomplete?

23 MR. DAVIS: Object to the form.

24

1 BY MS. FITZPATRICK:

2 Q. The company has to put all its known failure
3 modes that can lead to a risk of harm to patients on its
4 FMEA; right?

5 A. A known failure mode.

6 Q. Okay. And if it doesn't put a known failure
7 mode that can lead to a risk of harm to patients on its
8 FMEA, it hasn't completed the FMEA process; right?

9 A. The FMEA that you're looking at may be a user
10 FMEA, and so I can't say categorically that all FMEAs are
11 going to capture all potential risks all of the time. I'm
12 trying to establish that for you, that we have to go back
13 and assess where did we miss the understanding of the
14 product performance and, thus, not capture that risk? Was
15 it a process potential hazard or was it a -- was it a
16 user -- human factors? That's a big area, and design is
17 only one part of the FMEAs.

18 Q. Okay. So you've given me some examples of how
19 you believe that the FMEA may not be incomplete. Let me
20 ask you the reverse of that.

21 Using the hypothetical that I gave you,
22 can you tell me when an FMEA would be incomplete if a
23 company does not put a known failure mode that can lead to
24 a risk of harm to a patient in its FMEA?

1 A. If they misunderstood the input requirements.

2 Q. And is that the only way it could happen?

3 A. As I said, you could do an FMEA based on the
4 input requirement and the projection of a potential
5 failure mode. If someone isn't projecting that potential
6 failure mode, they wouldn't necessarily come up with the
7 potential risk.

8 Q. Well, you'd agree with me that could happen if
9 a company is sloppy; right?

10 A. No, ma'am. It can happen when people are
11 being very diligent. Designers may not know every
12 potential failure mode of every product they're working
13 on.

14 Q. And it can also happen if a company is being
15 sloppy about the way it does its FMEA; right? It can't
16 happen if a company is being sloppy?

17 A. I suppose sloppy people can make sloppy FMEAs.

18 MR. DAVIS: Let's take a break at some
19 point.

20 MS. FITZPATRICK: I'll give you a break
21 in just a second.

22 BY MS. FITZPATRICK:

23 Q. And it can happen if a company hasn't
24 undertaken the FMEA process with as much due diligence as

1 it should have; correct?

2 A. No, that can happen when they have not
3 understood all of the input requirements, nor -- or not
4 projected all of the potential failure modes. So there
5 are multiple ways that an FMEA can be incomplete.

6 Q. And it can also happen when one area of the
7 company knows of its potential failure mode and risk and
8 doesn't communicate it to the team of people who are
9 putting together the FMEA on a different product; correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: It's unlikely to happen
12 because the design team would organize the information
13 that is known by the company at the time they began their
14 design process.

15 BY MS. FITZPATRICK:

16 Q. That's what the design team should do;
17 correct?

18 A. That is a part of their requirements.

19 Q. And if the design team doesn't do that
20 correctly, it can lead to a situation where a known
21 failure mode that is associated with the risk of harm to a
22 patient doesn't end up on an FMEA; correct?

23 MR. DAVIS: Object to the form.

24 THE WITNESS: It's unlikely.

1 BY MS. FITZPATRICK:

2 Q. It can happen; can't it?

3 A. Anything can happen.

4 Q. If the process isn't done the way it should be
5 done, it can lead to a circumstance where a known failure
6 mode that is associated with risk of harm to a patient
7 does not appropriately show up on an FMEA; correct? It
8 can happen?

9 MR. DAVIS: Object to form.

10 THE WITNESS: If the process is done
11 correctly, it can still happen because we don't know
12 everything when we're in the early stages of design and
13 development.

14 BY MS. FITZPATRICK:

15 Q. Okay. So we know it can happen when the
16 process is done correctly.

17 My question to you is, it can also happen when
18 the process is done incorrectly; right?

19 A. That would be possible.

20 Q. Let's take a break.

21 (Whereupon, a recess was taken from
22 3:46 p.m. to 3:58 p.m.)

23 BY MS. FITZPATRICK:

24 Q. Ms. Duncan, in your experience, it would be

1 unusual for a company to have knowledge of a potential
2 failure mode with an attendant risk of harm to a patient
3 and not include that somewhere in its FMEA process;
4 correct?

5 MR. DAVIS: Object to form.

6 THE WITNESS: It would be unusual.

7 BY MS. FITZPATRICK:

8 Q. Let me go through some documents with you.
9 Let's mark this as Exhibit 12.

10 (Whereupon, Exhibit 12 was marked.)

11 BY MS. FITZPATRICK:

12 Q. Now, Ms. Duncan, do you recognize this from
13 Ms. Wilson's report?

14 A. Yes.

15 Q. Okay. And did you review this in connection
16 with your opinions that you gave in this case?

17 A. I reviewed her report. I did not use this
18 document as a part of my opinions.

19 Q. Okay. And I'm asking, did you review this
20 document, not --

21 A. I reviewed it as an attachment to her report.

22 Q. Okay. Is there anything in this document as
23 Ms. Wilson has set forth here that you believe is
24 inaccurate or wrong?

1 MR. DAVIS: If you're going to answer
2 that question, take your time to go through every line
3 item on the document.

4 THE WITNESS: Yes, and I have to get my
5 little magnifying glass because the print is too small to
6 read.

7 BY MS. FITZPATRICK:

8 Q. I wish you had an extra because I can't read
9 it, either. The purse looks good on you.

10 (Discussion off the record.)

11 MR. DAVIS: While she's looking at that,
12 I'm going to object to the form of the question because
13 you're -- when you ask her if she agrees -- disagrees with
14 anything on it, there's some interpretive -- it looks to
15 me there's some interpretations, so it's hard to say
16 what --

17 MS. FITZPATRICK: She can tell me if she
18 feels that.

19 THE WITNESS: May I borrow your
20 highlighter?

21 BY MS. FITZPATRICK:

22 Q. Absolutely.

23 A. Just one more minute.

24 Q. Sure.

1 A. Okay. I think I can answer your question
2 whether there's other items on here to which I would
3 object.

4 Q. Yep.

5 A. I think one of the first things I would
6 characterize as, I mean, not necessarily inaccurate but
7 not applicable is, for example, at December 2000, above
8 the line you see ISO 9001:2000, 3rd edition.

9 Q. Uh-huh.

10 A. That standard was specifically excluded from
11 being applicable to the medical device industry.

12 Q. Okay. So it's not incorrect, but you think
13 it's irrelevant to what we're doing?

14 MR. DAVIS: Object to the form. I don't
15 know what "incorrect" means.

16 THE WITNESS: The evolution of ISO
17 13485 was to specifically -- and it didn't happen at
18 once. It didn't happen until the 2003 version. The
19 ISO 13485 is explicit to medical device manufacturers.
20 There are certain contract manufacturers that may use
21 ISO 9001 generically, but it's not applied to the medical
22 device industry. That's Item Number 1.

23 BY MS. FITZPATRICK:

24 Q. But let me use your words since Mr. Duncan --

1 Mr. Davis had a problem with this.

2 It's not inaccurate, but you challenge the
3 relevance of it to the reports that we're dealing with
4 here; right?

5 MR. DAVIS: Let me just note my
6 objection because we may have interrupted the witness.
7 I'm not sure if the former question is still pending. We
8 haven't allowed her to -- I don't know. Go ahead. Just
9 note my objection.

10 BY MS. FITZPATRICK:

11 Q. You might want realtime next time because you
12 could probably follow it better that way.

13 So what else do you have?

14 A. As I said, ISO 9001:2000, 3rd edition, if the
15 text is correct, it is not a standard applicable
16 specifically to medical devices, and in fact, the 13485
17 explicitly takes over and instead of 9001:2000, 13485
18 applies to medical device quality-management systems.
19 There are similarities, but we would not meet our
20 obligations if we were using ISO 9000:2000 instead of
21 13485 for those countries where 13485:2003 are required.

22 The second item I need to point out to you is
23 where you look at July 1994 and you look at ISO 9001:1994,
24 in the same token, medical device component manufacturers

1 and some medical device manufacturers voluntarily
2 subscribe to that standard, but it was actually EN 46001,
3 which is an extension, if I may call it that, and it's
4 specific to medical device quality systems for those
5 products that received their approval to market -- excuse
6 me -- in Europe, and I don't see the Canadian version of
7 ISO 13485 on here, so that's number three.

8 Q. Is this -- is that a Canadian requirement or a
9 United States requirement?

10 A. ISO 13485 is not a U.S. requirement at all.

11 Q. You said, "I don't see the Canadian version of
12 ISO 13485."

13 Is it your opinion here that the Canadian
14 version of the ISO 13485 is applicable to the subject
15 matter that you've opined on here?

16 A. I'm trying to be even -- this is describing
17 13485. That's not applicable to the U.S. at all, anyway.
18 So 13485, since it's here, I was also just pointing out
19 that the Canadian adoption of that is also not on here.

20 And in addition, where we see some of the
21 lines --

22 Q. Uh-huh.

23 A. -- horizontal lines, the effective dates --
24 some of the standards are -- may be issued but may not

1 have been adopted, and so what's imprecise about the
2 timeline is the actual adoption date for some of these
3 standards, and I would also point out another one, is
4 that --

5 Q. I'm sorry, let me --

6 A. I'm on 5.

7 Q. Take those in order.

8 Which adoption dates are you referring to?

9 A. Well, as a for example, when a standard is
10 issued, different countries adopt them. So ISO 13485,
11 the chart here shows it in 1996, that has not been adopted
12 in the United States.

13 So if we were to make this timeline relevant
14 to the United States, it is not an adopted standard in the
15 United States. Any company may subscribe to a notified
16 body and go and pay that notified body -- excuse me,
17 registrar, ISO registrar. We can go and hire an ISO
18 registrar to come and audit our quality systems on a
19 voluntary basis and pay them for their time and trouble
20 and receive a certification to conformity, but it is not
21 an adopted standard in the United States.

22 Q. Here -- here's what I'm very confused about,
23 Ms. Duncan.

24 A. Okay.

1 Q. Where on this chart has Ms. Wilson made the
2 representation that ISO 13485, whatever iteration, was
3 adopted in the United States on any particular date?

4 A. Okay. So maybe I'm guilty of assuming. I was
5 assuming that the reason she went to this effort to create
6 this detailed chart was she was trying to have some
7 relevance to her report.

8 Q. Let me ask you again. Where on this chart --
9 she has indicated the dates that these ISO standards were
10 issued.

11 Are any of those dates wrong?

12 MR. DAVIS: Just the date on which it
13 was issued?

14 BY MS. FITZPATRICK:

15 Q. Uh-huh.

16 A. I would look to her on the dates they were
17 issued, but adoption is a very different thing, and
18 they're adopted in different countries at different times.

19 Q. But Ms. Duncan (sic) hasn't represented
20 anything about adoption on this; correct? You're reading
21 into that; am I correct, or am I missing the word
22 "adoption"?

23 MR. DAVIS: Object to the form. It's in
24 her report.

1 MS. FITZPATRICK: I asked about this.

2 MR. DAVIS: Well, that's part of her
3 report.

4 BY MS. FITZPATRICK:

5 Q. I know. Where on this -- let me make this --
6 you two are very confusing.

7 Where does it say "adoption" on this? Does it
8 say it anywhere?

9 A. She did not use the word "adoption." She
10 said, "Quality and risk management standards
11 implementation publication timeline."

12 So the implementation is germane to the
13 country. A publication is when the standard was printed
14 and produced. It can be printed and produced anytime. It
15 has to be implemented by adoption for it to even be
16 relevant to this topic, and since it was a section in her
17 report, on page 5, she says -- she refers to -- Figure 2,
18 Figure 1. Sorry, Figure 1 and 2 -- I can't recall. Was
19 this an exhibit?

20 Q. I want to make this so much simpler than
21 you do, Ms. Duncan, and I feel that we are very, very
22 far afield right now.

23 I gave you a one-page document called
24 Exhibit 12.

1 A. Right.

2 MS. FITZGERALD: And I would ask you not
3 to coach the witness. She can answer of her own account.

4 THE WITNESS: He's not coaching me.

5 BY MS. FITZPATRICK:

6 Q. He's pointing out --

7 A. My point --

8 Q. I want you to answer my question.

9 A. Yes.

10 Q. Because that's -- is there anything on this
11 one page that I gave you that is Exhibit 12 that is
12 inaccurate or incorrect?

13 A. As I have previously stated, this time chart
14 is inaccurate by omission and commission. It includes
15 standards that are not applicable to medical devices, and
16 it omits standards that are applicable to medical devices
17 in certain jurisdictions.

18 Q. Okay. So you just -- so you can't agree with
19 this?

20 MR. DAVIS: Let her finish her answer.

21 MS. FITZPATRICK: No, I'm not going to
22 waste the deposition on this.

23 MR. DAVIS: We're not going forward.

24 No. Just --

1 BY MS. FITZPATRICK:

2 Q. Is this accurate or not?

3 MR. DAVIS: We're not answering that.

4 We're not answering that question until you let her

5 finish. You want to withdraw the last question?

6 MS. FITZPATRICK: No, I want her to

7 answer the question.

8 MR. DAVIS: Let her finish answering,

9 then.

10 THE WITNESS: There are errors of

11 commission and omission, and I've said that already, and

12 that's where I'll stop.

13 BY MS. FITZPATRICK:

14 Q. And you were paid \$60,000 by Ethicon to reach

15 that opinion; correct?

16 I'm going to try another one. Maybe this will

17 be easier for you.

18 MR. DAVIS: Object to the form.

19 BY MS. FITZPATRICK:

20 Q. Let's go to Number 13. Can I have this one?

21 (Whereupon, Exhibit 13 was marked.)

22 BY MS. FITZPATRICK:

23 Q. Anything wrong with this one?

24 A. Well, obviously it's a --

1 MR. DAVIS: Object to form.

2 THE WITNESS: It's a photocopy out of a
3 standard, so the only thing I would say might be wrong
4 with it is you haven't given me a reference to where it
5 came from.

6 BY MS. FITZPATRICK:

7 Q. It came from Ms. Wilson's report.

8 Do you recognize this? Is there anything in
9 this that you disagree with?

10 A. As I've said, you've truncated the actual
11 document. The report, exhibit whatever, because it's been
12 marked through, so you have provided me only a section of
13 the entire flow chart, which, by the way, is a copyrighted
14 document, ISO 14971.

15 Q. You're talking about a totally different
16 chart. You're talking about this, which we'll mark as
17 Exhibit 14.

18 (Whereupon, Exhibit 14 was marked.)

19 BY MS. FITZPATRICK:

20 Q. Do you disagree with this?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: Would you please explain
23 to me where this comes from?

24

1 BY MS. FITZPATRICK:

2 Q. I'm talking about Exhibit Number 14.

3 Do you disagree with this?

4 A. Oh.

5 MR. DAVIS: Object to the form.

6 THE WITNESS: Is this the same chart as

7 in Ms. Wilson's report?

8 BY MS. FITZPATRICK:

9 Q. Why don't you take a look at it and tell me if
10 you disagree with it?

11 A. It is the same from her report?

12 Q. I asked you if you disagree with it. I didn't
13 ask if it was the same from her report.

14 MR. DAVIS: Object to the form.

15 THE WITNESS: What is there to disagree
16 with?

17 BY MS. FITZPATRICK:

18 Q. You tell me.

19 A. She's copied a document from a standard, and
20 I've agreed that they are the same.

21 Q. Do you believe that these are the correct
22 steps? Is there anything in here in this flowchart that
23 you disagree with this document?

24 MR. DAVIS: I object to the form.

1 THE WITNESS: As I said, she copied it
2 from a standard. There's nothing for me to agree or
3 disagree with it about.

4 BY MS. FITZPATRICK:

5 Q. Okay. So you don't disagree with it?

6 A. I have no basis for agreement or disagreement.
7 She copied it from an international standard.

8 Q. I understand you're telling me where it came
9 from. I'm asking you a different question.

10 This -- when this shows up at trial, you're
11 going to say, "Yes, that's accurate, that's completely
12 right, I've got no problem with that;" correct?

13 MR. DAVIS: Object to the form.

14 THE WITNESS: I believe it is an
15 accurate photocopy.

16 BY MS. FITZPATRICK:

17 Q. Is it an actual -- is it an accurate
18 depiction of the risk analysis and risk control process?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: I will, again, point to
21 you that she has taken this out of 14971:2000. When I
22 compared the two, they are the same. Without seeing where
23 this came from, I can't say anything more than that,
24 ma'am.

1 BY MS. FITZPATRICK:

2 Q. Did you just tell me where it came from?

3 A. I told you they're identical; okay? But there
4 are many versions of 14971, and without looking at those
5 versions, I would not hazard to claim that they are
6 identical. I'm saying the two are good photocopies of one
7 another.

8 Q. We're going to be here for a long time. Let
9 me tell you what you just said to me in the last two
10 minutes.

11 "I will again point out to you that she has
12 taken this out of 14971:2000. When I compare the two,
13 they are the same. Without saying where this came, I
14 can't say for" --

15 Didn't you just tell me where it came from?
16 Is it 14971:2000, or not?

17 MR. DAVIS: Object to form.

18 THE WITNESS: The images are similar
19 with the exception of her writing.

20 BY MS. FITZPATRICK:

21 Q. Is what I showed you and what you have as
22 Ms. Wilson's report, as produced in this case without
23 handwriting, did this come from 14971:2000 as you told me
24 not only a minute ago?

1 A. I agree that it is the same photocopy that is
2 in her report marked 14971:2000. I don't have other
3 standards in front of me to compare. I will accept it
4 as -- from her report.

5 Q. Okay. Let's see what we can do, here.

6 (Whereupon, Exhibit 15 was marked.)

7 BY MS. FITZPATRICK:

8 Q. Ms. Duncan, have you seen this document
9 before?

10 A. It looks familiar.

11 Q. Did the lawyers for Ethicon provide you this
12 document when you prepared your report in this case?

13 A. To be certain, I would have to check the Bates
14 numbers, but it looks familiar.

15 Q. Okay. And is this something that you
16 considered in reaching your conclusions in this case?

17 A. I recall reading it and reviewing the
18 information that was here, yes.

19 Q. And you'll see that it's dated 1992; correct?

20 A. Yes, ma'am.

21 Q. And you'll agree with me that is prior to
22 Ethicon's acquisition of Medscand and the TVT-R mechanical
23 cut device; correct?

24 A. It would be prior to that.

1 Q. I want you to look on your "IR" and "IR
2 Microspectroscopy" on the first page; correct?

3 A. Yes.

4 Q. Okay. And "IR examinations were done for all
5 explants."

6 Do you understand that IR examinations were
7 done for explants of PROLENE sutures in this study?

8 A. Yes.

9 Q. And PROLENE is the same material that the
10 TVT-R mechanical cut mesh is made of; correct?

11 A. That's correct.

12 Q. Have you -- in all of the documents that you
13 have reviewed in this case, have you seen any evidence
14 that Ethicon did any studies on any explants of vaginal
15 mesh?

16 A. Of what?

17 Q. Vaginal mesh, any of its pelvic mesh products
18 made with PROLENE?

19 A. Yes, I recall some additional studies.

20 Q. Okay. And what studies do you believe that
21 Ethicon conducted on explanted PROLENE pelvic mesh?

22 A. Well, one study, if you would go to my -- it's
23 Exhibit A in medical literature, the first item called "A
24 14-day Rabbit Study," it's my recollection that those were

1 mesh -- that was a mesh study.

2 Q. And do you believe that that was an IR
3 examination that was done on explanted pelvic mesh?

4 A. Oh, I'm sorry, I thought your question was,
5 did I know of any other explants studies.

6 Q. Huh-huh. It wasn't my question.

7 A. I would have to say I don't recall. I could
8 look in the record if you would want me to, but I cannot
9 recall at this time.

10 Q. Okay. But you'll agree with me that, as of
11 1992, Ethicon knew how to do IR examinations for explanted
12 PROLENE products; correct?

13 A. I presume they knew how to do it.

14 Q. Okay. And in fact, this document shows that
15 they actually had done IR examination for explanted
16 PROLENE sutures at that time; right?

17 A. Sutures.

18 Q. Okay.

19 A. Yes, ma'am. I believe -- if I may correct
20 something, I do recall additional studies of mesh, and
21 I cannot recall whether or not Ethicon conducted them.
22 I may have read that in a publication, so I would
23 stand by what I said. I don't recall that Ethicon did
24 them, but I believe I recall seeing another IR study.

1 Q. Okay. And in fact, based on your work back in
2 the 1980s on silicone breast implants, you participated at
3 that time in meetings where they discussed the retrieval
4 of explanted silicone breast implants; correct?

5 A. Actually, no, I didn't. My work was limited
6 to -- I'll let you two finish.

7 Q. No, your work was limited to --

8 A. I was an engineer on the acquisition project
9 for 3M Company, and I did an analysis of -- on
10 not-yet-implanted silicone breast implants, and so I was
11 deposed because of that memo, and although I was involved
12 in the acquisition transition team, I did not personally
13 look at any explanted silicone breast implants.

14 Q. What I asked you -- what I asked you is, back
15 in the '80s when you worked on the silicone breast implant
16 litigation, you agree with me the medical device companies
17 that had permanent medical devices conducted implant
18 retrieval meetings.

19 And you actually participated in those;
20 correct?

21 A. Implant retrieval meetings?

22 Q. Uh-huh.

23 A. Well, I was a workshop chairman for implant
24 retrieval meetings hosted by the Society for Biomaterials.

1 Q. Okay.

2 A. But I didn't participate in those. I was the
3 host of the meeting and I listened to the presentations.

4 Is that --

5 Q. So hosting the meeting --

6 A. I was the chairman of the meeting.

7 Q. You were the chairman of the meeting but you
8 didn't participate in the meeting.

9 Is that what you're saying?

10 A. I didn't say I didn't participate in the
11 meetings.

12 Q. Ma'am --

13 MR. DAVIS: Wait. No, let her finish
14 her answer.

15 THE WITNESS: You asked me in the 1980s
16 when I was -- I thought you were talking about my
17 activities at 3M Company.

18 BY MS. FITZPATRICK:

19 Q. Ma'am, I asked you about --

20 A. Just repeat the question.

21 Q. Sure, because I think this is one where we may
22 have --

23 Back in the 1980s when you worked on silicone
24 breast implants, you agree with me that medical device

1 companies had implant retrieval meetings; correct? That's
2 what you called it, "Implant retrieval meetings?"

3 A. I was the workshop chairperson on behalf of
4 the Society for Biomaterials for Implant Retrieval, and
5 some of the participants of that abstracted meeting -- you
6 had to make an abstract and put it in for the meeting --
7 some of the participants may have been silicone breast
8 implant manufacturers. I can't personally recall. I'd
9 have to pull up the abstracts for the meeting. I was the
10 chairperson and helped to organize the meeting.

11 Now, that's a very different thing from asking
12 me if I was a party to a silicone breast implant retrieval
13 meeting.

14 Q. I think we're slicing and dicing it. Let me
15 get you -- out of fairness, let me get you the two
16 questions and answers, and maybe then you can understand
17 what my confusion is.

18 Your answer is: "Well, I was the workshop
19 chairman for implant retrieval meetings hosted by the
20 Society for Biomaterials, but I didn't participate in
21 those. I was the host of the meeting and I listened to
22 the presentations. I was the chairman of the meeting."

23 And next question: "You were the chairman of
24 the meeting but you didn't participate in the meeting; is

1 that what you're saying?"

2 Answer: "I didn't say I didn't participate in
3 the meetings."

4 I have a direct quote from you that says, "I
5 didn't participate in those."

6 Did you participate or not?

7 A. If you would go back further to the original
8 question, I think I can straighten this out.

9 Q. Great. Tell me how I've got it wrong.

10 A. Can you read back her original question about
11 silicone breast implants?

12 Q. Well, the question is, I asked you -- or you
13 told me that you were the workshop chairman for implant
14 retrieval meetings hosted by the Society for Biomaterials
15 "but I didn't participate in those."

16 And then I said, "So what you're saying is,
17 you were the chairman of the meeting but you didn't
18 participate in the meeting," trying to clarify it, and you
19 said, "I didn't say I didn't participate in a meeting."

20 Let's just scratch and go back.

21 A. I asked you to go back to the original
22 question that got us off track and you don't want to do
23 that and I don't know why.

24 Q. Did you participate --

1 A. It started with in the 1980s. Go back to that
2 question and I'll try to clarify.

3 Q. Did you -- here's how we can clarify this.

4 Did you --

5 MR. DAVIS: Let her ask the question.

6 BY MS. FITZPATRICK:

7 Q. Did you participate in implant retrieval
8 meetings concerning silicone breast implants?

9 A. I participated in an implant retrieval
10 symposium, and there may have been participants there who
11 gave presentations on silicone breast implants, but it was
12 multiple-layered workshops in various parallel sessions,
13 and I honestly cannot recall at this period of time if I
14 sat in on those sessions or not.

15 Q. Okay. Were there other sessions involving
16 implant retrieval meetings associated with other medical
17 devices beyond just the silicone breast implants?

18 A. Please repeat the question.

19 Q. Sure. Did these implant retrieval meetings
20 involve retrieval of other medical devices beyond just the
21 silicone breast implants?

22 A. As well as I recall, yes. It was open to
23 anyone who had an implant.

24 Q. And do you recall what implants were discussed

1 there?

2 A. I can recall temporomandibular joints, I can
3 recall that there were vascular grafts, I can recall there
4 were probably polyethylene hip caps. But there were
5 probably dozens more. I can't recall.

6 Q. Do you know whether Ethicon has ever
7 participated in any implant retrieval meetings associated
8 with the pelvic floor polypropylene device that it sells?

9 A. I wouldn't have any way of knowing that.

10 Q. Did you ask Ethicon that?

11 A. No, I did not ask Ethicon that.

12 Q. Okay. We go to page 2 of the document that I
13 just gave you, under "Conclusions."

14 Am I reading it correctly when it says that
15 "Degradation in PROLENE is still increasing as part of
16 this study"?

17 A. You didn't read the entire sentence.

18 Q. Okay. "Degradation in PROLENE is still
19 increasing and PVDF. Even though a few cracks were found,
20 it is still, by far, the most surface-resistant in-house
21 made suture in terms of cracking."

22 A. Yes.

23 Q. Does that state that degradation was occurring
24 in the PROLENE sutures?

1 A. Increasing -- the context is, "Increasing with
2 respect to time within the context of this experiment."

3 Q. Okay. So in the context of this experiment,
4 you'll agree with me that Ethicon concluded that the
5 longer the PROLENE suture stayed in, the more degradation
6 Ethicon saw on that suture; right?

7 MR. DAVIS: Let me object, and that's a
8 broad question. If you need to read any of the document,
9 you're entitled to read it before you answer the question.

10 THE WITNESS: Well, I -- yes, I would
11 like to ask you where you were reading that from?

12 BY MS. FITZPATRICK:

13 Q. I'm basing that on the question -- I'm just
14 trying to understand the answer that you gave me.

15 And so what I'm asking is, you looked at this
16 document and you considered it when you formed your
17 opinions in this case; correct?

18 A. I looked at this document, yes.

19 Q. Okay. And what you told me is that increasing
20 the context is, "Increasing with respect to time within
21 the context of this experiment."

22 And what I asked you is, does that mean that
23 the longer the PROLENE suture was implanted, the more
24 degradation that Ethicon saw on that suture?

1 MR. DAVIS: My only comment, you're free
2 to read whatever you need to read in the document.

3 THE WITNESS: Okay. You asked me if it
4 is increasing, and from the conclusion here, for -- I'm
5 sorry, when -- if you go up to the "inherent viscosity."

6 BY MS. FITZPATRICK:

7 Q. Uh-huh.

8 A. The first conclusion is, "No significant
9 differences were seen in inherent viscosity after one and
10 two years."

11 Q. Okay. So the inherent viscosity was
12 determined on the ETHILON and the NOVAFIL sutures;
13 correct?

14 A. You're correct.

15 Q. It's just very simple.

16 Does this document say that degradation in
17 PROLENE is still increasing? It says that in Bullet 2
18 under "Conclusions;" right?

19 A. Well, and conclusions Bullet 1, the seven-year
20 in vivo results generally substantiated five-year
21 findings. So I'm -- and then, what I don't know from what
22 he means, then, he goes on with the second bullet, and
23 says, "Is still increasing." So I don't know if he means
24 increasing relative to Number 1 explants or still

1 increasing between 5 and 7. It isn't clear, but he is
2 saying it is still increasing, and I don't quite
3 understand that in the context of the report.

4 Q. Okay. So whether you understand it or not --
5 and we don't need to debate it, it does state in this
6 report that -- so you'll agree with me that the report
7 looked at degradation of PROLENE sutures; correct? That's
8 one of the things they looked at?

9 A. That's one of the things they were trying to
10 determine.

11 Q. And one of the things that they concluded is
12 degradation of PROLENE is still increasing as of this
13 October 15, 1992 memo that I gave you?

14 A. And as I said, the conclusions are not
15 consistent with other parts of the report, so I -- I
16 understand that happens from time to time on reports.

17 (Whereupon, Exhibit 16 was marked.)

18 BY MS. FITZPATRICK:

19 Q. I'm showing you what's marked as Exhibit 16.

20 You've seen this document before; haven't you?

21 A. I recall seeing it but I didn't consider it as
22 part of my due diligence activity.

23 Q. Okay. So you'll agree with me that this
24 document relates to PROLENE polypropylene mesh; correct?

1 A. As I said, I'll have to look at it in more
2 detail.

3 Q. Sure.

4 A. Because I didn't consider it as part of my
5 scope of work.

6 I'm looking for my blue picture.

7 MR. DAVIS: What are you looking for?

8 THE WITNESS: The Ethicon mesh timeline.

9 MR. DAVIS: It's a single page.

10 THE WITNESS: Yeah. Let me see. Yes.

11 Thank you. I want to be sure I understand what they're
12 talking about, here.

13 All right. So what is your question, then?

14 BY MS. FITZPATRICK:

15 Q. You understand that this relates to PROLENE
16 mesh; correct?

17 A. It is a specific indication for use using
18 PROLENE.

19 Q. It deals with PROLENE mesh; correct?

20 A. There is a PROLENE mesh in the introduction,
21 yes.

22 Q. Okay. And you know that the TVT retropubic
23 mechanical cut is made with PROLENE mesh; correct?

24 A. That's correct.

1 Q. And in this particular document, Ethicon, in
2 1998, is considering some of the disadvantages of that
3 PROLENE mesh when used for pelvic organ prolapse repair;
4 correct?

5 A. That's correct.

6 Q. Okay. And I want you to take a look at some
7 of the -- what they call main concerns. I don't want to
8 have a disagreement with you over that word again, but
9 main concerns that have arisen as of the end of 1998 with
10 using PROLENE mesh for pelvic organ prolapse repair.

11 Do you see that right at the bottom of the
12 page 9030?

13 A. Main reason, is that --

14 Q. The main concerns.

15 A. I see it, the main reason for dissatisfaction,
16 or you're looking at another paragraph.

17 Q. No, I'm looking right at the bottom. "However
18 the main concerns that have arisen so far are." And then
19 it stops.

20 A. Oh.

21 Q. And they identify here a problem or concern
22 with fear of rejection.

23 Is that a potential failure mode?

24 A. Actually, not to my knowledge. Fear of

1 rejection -- not to my knowledge. I have no knowledge of
2 PROLENE being rejected by the body.

3 Q. Okay. I'm not asking whether you have
4 knowledge of that.

5 Was fear of rejection of PROLENE by the body
6 identified as a concern of using PROLENE mesh for a pelvic
7 organ prolapse repair?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: The memo is saying that.
10 I don't understand why it would.

11 BY MS. FITZPATRICK:

12 Q. Okay. And it also identifies here another
13 concern of problems with removing the mesh at a later
14 date; correct?

15 A. Again, with respect to the prolapse, I can
16 understand what they may have been looking at. I, again,
17 don't have expertise in this field. This is not what I
18 was -- this is outside my scope.

19 Q. Is that is a potential failure mode?

20 MR. DAVIS: Object to the form.

21 THE WITNESS: I can't speak to that
22 because this is a -- this is a marketing document, and I
23 don't see a potential failure mode described here. Again,
24 fear is not necessarily a failure mode.

1 BY MS. FITZPATRICK:

2 Q. I asked you if problems with removing mesh at
3 a later date is a potential failure mode?

4 A. It's a fear. He says right here, "The main
5 concerns that have arisen so far is a fear of rejection
6 and a fear of problems removing mesh at a later date."
7 That is not a failure mode of the mesh.

8 Q. You don't think that the body -- the
9 possibility of the body rejecting the mesh is not, in your
10 mind, a failure mode associated with the mesh?

11 MR. DAVIS: Object to the form.

12 THE WITNESS: Ma'am, rejection in the
13 medical art for biomaterials and materials for use in
14 implants has a specific connotation, and rejection is --
15 is not known to have occurred for synthetic materials.
16 Rejection is an immune response to a natural tissue.

17 BY MS. FITZPATRICK:

18 Q. That's what your testimony is, today? Let's
19 leave that one aside.

20 Problems with removing the mesh at a later
21 date.

22 A. That's what -- (inaudible.)

23 Q. That's a potential -- but a failure mode
24 doesn't have to be proven. I thought we'd already

1 discussed, you put in all known failure modes and
2 foreseeable potential failure modes; correct?

3 Ethicon here has identified potential failure
4 modes associated with the use of the PROLENE mesh.

5 It's such an easy question. What's the
6 problem?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: This is a discussion
9 document. It is not a failure modes effects analysis.

10 BY MS. FITZPATRICK:

11 Q. That's exactly my point.

12 MR. DAVIS: Let her finish her answer.

13 THE WITNESS: The specific words he has
14 used here, to be precise, are "fear." That is not a known
15 failure mode. It may, under certain circumstances, if we
16 were to analyze a specific input requirement, we might
17 determine that there are failure modes like this, but this
18 specific document is talking about fear. It's not a known
19 failure mode.

20 BY MS. FITZPATRICK:

21 Q. Did we not already establish that you put in
22 known failure modes and potential, foreseeable failure
23 modes; correct?

24 A. And neither of these two fears meet your own

1 description.

2 Q. You don't believe that the inability to remove
3 mesh once it's been implanted is a potential failure mode
4 for a PROLENE mesh.

5 Is that your testimony?

6 MR. DAVIS: Object to the form.

7 THE WITNESS: This memo is not
8 discussing a known failure mode or a potential failure
9 mode. They are discussing a fear.

10 BY MS. FITZPATRICK:

11 Q. Okay. Please answer my question.

12 Is the inability to remove mesh once it's been
13 implanted a potential failure mode for PROLENE mesh? Yes
14 or no?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: It is not designed to be
17 removable; so therefore, not being removable is not a
18 failure mode.

19 BY MS. FITZPATRICK:

20 Q. Okay. Concern about mesh eroding into the
21 bladder or the rectum, you would agree with me, I'm
22 assuming, that erosion of mesh into adjacent organs is a
23 potential failure mode that should be included in a risk
24 hazard analysis; correct?

1 MR. DAVIS: Object to the form.

2 THE WITNESS: Excuse me, ma'am, but it
3 is not a failure mode of the mesh. It may be a risk
4 associated with the surgical placement of mesh, but is not
5 a failure mode of the mesh.

6 BY MS. FITZPATRICK:

7 Q. What if Ethicon called it a failure mode?
8 Who's right; you or Ethicon?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: That's hypothetical. If
11 you want to show me a document, I'd be happy to --

12 BY MS. FITZPATRICK:

13 Q. I'm very happy to do that.

14 "Concern about stiffness of the mesh and the
15 risk of mesh protruding through the vagina."

16 Again, you don't see this as a potential
17 failure mode for the mesh; is that correct?

18 MR. DAVIS: Object to the form.

19 THE WITNESS: It may be a risk of a
20 surgical procedure and a surgical use of the mesh. It is
21 not a failure mode of the mesh.

22 BY MS. FITZPATRICK:

23 Q. Do you believe that as a risk of the surgical
24 procedure and the surgical use of the mesh, it should have

1 been included in an FMEA on the TVT-R mechanically-cut
2 FMEA?

3 MR. DAVIS: Object to the form. This
4 has nothing to do with TVT, this document.

5 MS. FITZPATRICK: That's fine.

6 THE WITNESS: Excuse me, you'll have to
7 ask me the question again.

8 BY MS. FITZPATRICK:

9 Q. Do you believe that, as a risk of the surgical
10 procedure and the surgical use of mesh, it should have
11 been included on an FMEA for the TVT-R mechanically-cut?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: Should have been? That's
14 asking me to conclude that it wasn't, and I don't have
15 information in front of me right now to make that
16 conclusion. If you'd like to show me a document, I can
17 discuss it.

18 BY MS. FITZPATRICK:

19 Q. Do you recall ever seeing it on an FMEA?

20 A. I saw a lot of different FMEAs, so I'm not
21 going to speculate at this hour.

22 Q. Let's look at 9032. Under, "Ability to shape
23 mesh," it states, "No frayed ends should be left which may
24 fall off into patient."

1 Do you see that?

2 A. Help me out, here. Where are you?

3 Q. We're right at the bottom, here (pointing).

4 A. All right. Thank you. This is, basically, a
5 performance requirement statement, basically, a wish list.

6 So we would take this as part of our input requirements.

7 This is an input requirement.

8 Q. Something that should have been considered;
9 correct?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Should have been
12 considered for the GyneMesh II, new mesh design.

13 So I believe --

14 BY MS. FITZPATRICK:

15 Q. So you don't think this should have been
16 considered for products that were used in the GyneMesh 1
17 that have possibly frayed ends which could be left and
18 fallen off into the patient?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: It's my understanding that
21 mesh fraying was extensively considered.

22 BY MS. FITZPATRICK:

23 Q. And if you can take a look at 9034, there's a
24 subsection, "Stiffness." And it says, "The mesh, and in

1 particular the edges, should not be sharp in any way or
2 in any way contribute to the possibility of erosion
3 through the vaginal wall, bladder, or rectum."

4 Do you see that?

5 A. Yes, ma'am. I see it.

6 Q. And do you agree with me that Ethicon, in
7 connection with the development of this GyneMesh II, saw
8 potential problems arising from sharp edges on the mesh
9 and in pelvic space?

10 MR. DAVIS: Object to the form.

11 THE WITNESS: Again, this is an inputs
12 requirement, at best. It's a marketing document. It's a
13 proposal for a design, and so I think you've gone a little
14 further than the document's intention.

15 BY MS. FITZPATRICK:

16 Q. You agree with me, though, that a company
17 should gather information from all its experiences and all
18 its departments when it's creating a risk form on an FMEA
19 for a particular product; correct?

20 MR. DAVIS: Objection to form.

21 THE WITNESS: I believe that it's common
22 that that happens, and clearly, this is an example of how
23 Ethicon was attempting to gather a wide variety of
24 information, including some suggested input requirements.

1 BY MS. FITZPATRICK:

2 Q. Okay.

3 MR. DAVIS: Let's take a break, but I'll
4 let you get to a stopping point.

5 BY MS. FITZPATRICK:

6 Q. Do you believe that these input requirements
7 were considered for the TVT-R mechanical cut device?

8 MR. DAVIS: Object to the form.

9 THE WITNESS: Ma'am, this document was
10 outside the context. This was 1998, and this document was
11 not available to the original designers of the mesh, and
12 so I can't say how they did or if they did consider any of
13 the information in this document.

14 BY MS. FITZPATRICK:

15 Q. Okay. Fair enough. Let me show you the next
16 document.

17 MR. DAVIS: Do that and then let's take
18 a break.

19 MS. FITZGERALD: Can we mark this as 17?

20 (Whereupon, Exhibit 17 was marked.)

21 MR. DAVIS: Counsel, just one question.

22 If you're going to be a long time on this document, we
23 ought to go take a break now. If you're going to be a
24 short time, that's fine.

1 MS. FITZPATRICK: Not too long.

2 MR. DAVIS: I didn't want to interrupt
3 your thought.

4 MS. FITZPATRICK: I'm not going to be
5 too long. It will be a natural break point after this.

6 BY MS. FITZPATRICK:

7 Q. Okay. Ms. Duncan, I've shown you a document,
8 and you recognize this document; correct?

9 A. Yes.

10 Q. And this is something that you considered and
11 relied on for your opinion -- I'm sorry.

12 MR. DAVIS: Look at the entire document.

13 THE WITNESS: Yes, I understand to do
14 that, yes.

15 MR. DAVIS: I don't believe this was on
16 your list.

17 THE WITNESS: This is not a document
18 I've seen before this time.

19 BY MS. FITZPATRICK:

20 Q. Ethicon didn't provide you with this document?

21 A. Ma'am, I don't recall reviewing this document.
22 This document is a draft and it's unsigned. The one I
23 referenced was signed and later.

24 Q. Okay. All right. Let me get you a copy of

1 that.

2 A. I'm sorry?

3 Q. They showed you this; right? You're not
4 telling me that you didn't look at this; right?

5 MR. DAVIS: She's telling you she saw
6 the signed version.

7 MS. FITZPATRICK: No, I'm asking her. I
8 don't need to you testify.

9 MR. DAVIS: She may.

10 THE WITNESS: I saw a signed version,
11 which I presume is a later version of this document. This
12 is not the document that I reference in my report, and it
13 is not the document to which I -- for which I used in my
14 due diligence. Until you handed me this, I had not seen
15 this document.

16 BY MS. FITZPATRICK:

17 Q. You had not seen that document, so that was
18 not provided to you as part of --

19 A. No, I'm not saying it was not provided to me.
20 It may have been one of the ones I tried to look at, but
21 when you take this document and look at it in a host
22 of other documents, you may think you're looking at the
23 same document. This document was not signed and so,
24 therefore, I know, looking at it, that this is not the

1 document I was looking at.

2 Q. Okay. Let me show you a number -- let's mark
3 this as Number 18.

4 (Whereupon, Exhibit 18 was marked.)

5 MR. DAVIS: 18?

6 THE WITNESS: And your question?

7 BY MS. FITZPATRICK:

8 Q. What's the date of this document? Why don't
9 you take a look at the back page.

10 A. I'm sorry.

11 Q. It's either August 5th, 2001 or May 8th, 2001,
12 if you look on the very last page; correct?

13 MR. DAVIS: I think the standard in
14 Europe is to use the --

15 MS. FITZPATRICK: Yeah, I don't know.
16 I'm assuming it's May 2001.

17 BY MS. FITZPATRICK:

18 Q. Do you see these signatures?

19 A. I believe there -- there was a company cover
20 memo that had a date on it, and that would have been the
21 proper reference to the date, I think, so --

22 Q. 2001, good enough.

23 A. You can choose the date.

24 Q. We'll go with 2001. This was done after

1 Ethicon had acquired the TVT-R mechanical cut; correct?

2 A. Yes, ma'am.

3 Q. And this was done after the TVT-R mechanical
4 cut had been on the market, had been sold and implanted
5 into women; correct?

6 A. I'm having a hard time hearing you. You
7 dropped your voice.

8 Q. This was done after the TVT-R mechanical cut
9 had been in the market and had been sold and implanted
10 into women; correct?

11 A. Yes, ma'am.

12 Q. Okay. And it was done after the 1992 memo
13 that I showed you concerning the -- that had the statement
14 about the degradation of PROLENE sutures; correct?

15 A. Are you speaking of this one (pointing)?

16 Q. Uh-huh.

17 A. That was Exhibit 15.

18 Q. It was done after that; right?

19 A. Yes, ma'am.

20 Q. And it was also done after this August 1998
21 GyneMesh II, GyneMesh design document that I showed you;
22 correct?

23 A. That was '98, so yes, that is true.

24 Q. Okay. And can you identify for me on this

1 document where, if anywhere, Ethicon identified
2 degradation as a potential hazard associated with the use
3 of PROLENE mesh and the TVT-R mechanical cut?

4 A. There are a couple of places I'd like to point
5 out to you, so this is not -- I'm going to take them in
6 sequence.

7 Q. Sure.

8 A. If you go to line item 16 where we see, "Loss
9 of mechanical integrity."

10 Q. Is it your opinion that that means degradation
11 of the PROLENE mesh?

12 A. What we would be looking at is the potential
13 hazard. If you look at this particular style of FMEA,
14 they've done it in a different way. In fact, they call
15 it -- it's not considered a process FMEA, it's a design
16 review, and so the -- this is a -- considered a hybrid
17 style of design and user-hazard analysis, so we have to
18 take it in line item.

19 And so I would take you to number -- first to
20 number 16 where they talk about loss of mechanical
21 integrity. So if we were to have degradation of material,
22 there would be -- loss of mechanical integrity would be
23 its manifestation. That would be its effect, and they
24 send us to see 19A and G.

1 Now, let me go a little further.

2 Now, when we go down -- it's not a good one.

3 Okay. Go to -- they're sending us to 19A and G, so when
4 you go down further, the first time you see mechanical
5 property A, they're discussing needles. So go further,
6 and you see on G, there is -- no, I'm sorry, go to E,
7 "strength of mesh" in vivo. And in this context of
8 the source, this is how you have to read to this
9 document. The second column is source, and they're
10 saying strength of mesh in vivo/in vitro, that being a
11 hazard is not imaginable as they have as a source, either
12 the manufacturer, the user or -- not the third. It's
13 surgeon, manufacturer --

14 Q. User?

15 A. Thank you, user. So they have considered it
16 here as not imaginable.

17 And then for composition, if a mesh
18 biocompatibility, not imaginable, and I believe that's
19 the materials in this.

20 Q. Okay. So let me just ask a couple questions
21 and then we'll take a break.

22 It's your opinion, Ms. Duncan, sitting here,
23 that Ethicon appropriately considered the potential of
24 degradation of the PROLENE mesh when doing this design

1 review, and that's reflected in line items 16, 19E and
2 19GB; is that correct? Those are the three places?

3 A. I believe that's the -- let me just see if
4 there's anything else.

5 Well, to some extent, this is Number 5 line
6 item, systemic toxicity, a biocompatibility testing might
7 be an indirect consideration for degradation. So I would
8 say that they have three places, at least, where they have
9 considered degradation.

10 Q. And just let me clarify. So the line items
11 16, 19E and 19GB that you first directed me to, Ethicon
12 didn't fill in the box for exposition potential
13 consequence; correct?

14 A. That would be consistent with their method,
15 because if they haven't identified the source, they would
16 not complete the rest of this document.

17 Q. They didn't identify a failure mode; correct?

18 A. They categorized the source. If -- their
19 SOP said go through this column, then go through this
20 column, then go through this column. So if there's
21 nothing in the source column, they don't go to the next
22 column over.

23 Q. They didn't identify a failure mode; correct?

24 A. They assessed the potential for a failure mode

1 in the sense that they looked at the potential for a
2 hazard. Remember, this is a hazard.

3 Q. She's not answering the question.

4 MR. DAVIS: She is.

5 BY MS. FITZPATRICK:

6 Q. Does failure mode have anything filled in on
7 it?

8 MR. DAVIS: Don't answer that question.

9 No, we're not going forward until you let her finish or
10 you can withdraw the last question, either way.

11 BY MS. FITZPATRICK:

12 Q. Withdraw the question and let me ask you.

13 Does the line -- does the column "failure
14 mode," is that filled in line items 16, 19E or 19GB?

15 A. I don't see them filled in for 19 because
16 it's --

17 Q. It's a "yes" or "no."

18 A. Because that is a col -- that is a category.
19 So to go to 19, that is a category. So that wouldn't be
20 filled in, and you're saying 19A?

21 Q. No, I said 16, 19E or 19GB.

22 Is there anything written in a failure mode
23 column?

24 A. Well, 16 directs you to 19A and G. So there

1 would -- that whole entire row is not completed because
2 they're directing you down. They're trying to avoid
3 duplication. So then they go to 19, and G begins on the
4 other page. Get through the needle part. So in "Mesh" A
5 and B and ABA, BB, C, D, they are assessing the mesh.

6 Q. Ms. Duncan --

7 A. Mechanical properties of --

8 Q. Please answer my question.

9 MR. DAVIS: Wait.

10 MS. FITZPATRICK: I'm not wasting my
11 deposition on this nonsense anymore.

12 MR. DAVIS: No --

13 BY MS. FITZPATRICK:

14 Q. I asked you very specifically, 16, 19E, and
15 19GB, is there anything written in the failure mode
16 column? That is the only question that is pending at the
17 moment.

18 Yes or no?

19 MR. DAVIS: That's the exact question
20 she answered.

21 MS. FITZPATRICK: Really? And what is
22 19AB, ABA, ABB, ABC have to do with my question about 19E?
23 Nothing.

24

1 BY MS. FITZPATRICK:

2 Q. Is there anything written in 19E, failure mode
3 column, period?

4 MR. DAVIS: Do not answer the question
5 until she lets you finish your answer.

6 MS. FITZPATRICK: I've withdrawn every
7 question on the table except for one.

8 BY MS. FITZPATRICK:

9 Q. Is there anything written in the 19E failure
10 mode column?

11 MR. DAVIS: Just answer that question.

12 THE WITNESS: Just a moment.

13 MR. DAVIS: She doesn't want to know
14 about the others. Just answer that.

15 THE WITNESS: As I have explained before
16 on E, it would not be completed. The entire row would not
17 be completed because they didn't go past the source of the
18 hazard. This is a different style than you may be
19 accustomed to. It is not a true failure modes and effects
20 analysis style.

21 BY MS. FITZPATRICK:

22 Q. Is there anything written in the column is my
23 question. Not why.

24 MR. DAVIS: No.

1 MS. FITZPATRICK: This is preposterous.

2 BY MS. FITZPATRICK:

3 Q. Is there anything written in that column or
4 not?

5 MR. DAVIS: She said it, and then she's
6 explaining.

7 MS. FITZPATRICK: The answer is, "As I
8 have explained before, it would not be completed
9 because --" Give me a yes or no.

10 BY MS. FITZPATRICK:

11 Q. Does it say anything or not?

12 MR. COMBS: Okay. We're not going to
13 yell at the witness.

14 MS. FITZPATRICK: I am yelling. You're
15 darn right I am very upset right now because this witness,
16 for whatever reason, has been paid so much money by
17 Ethicon that she can't even say, "Yes, the column is
18 blank."

19 MR. COMBS: You know, Fidelma --

20 THE WITNESS: Ma'am, that is my
21 procedure.

22 MR. COMBS: Wait. You don't get to
23 scream at people. You don't.

24 MR. WALLACE: She's not screaming, first

1 of all.

2 MR. COMBS: She is.

3 MS. FITZPATRICK: You're right; I'm
4 agitated right now. I will freely admit I'm agitated on
5 the record because I have just spent -- and I love this,
6 because it's going to make a great record for me -- I have
7 spent seven minutes trying to get an answer to, "Does 19E
8 have anything written in the failure mode column?"

9 MR. DAVIS: She said --

10 MR. WALLACE: She did not say that. She
11 has never said that once.

12 MR. DAVIS: See if you can answer that
13 question yes or no.

14 THE WITNESS: Can I just please state --

15 MS. FITZPATRICK: It's yes or no.

16 MR. WALLACE: Answer the question.

17 MR. DAVIS: This time say yes or no and
18 then give your explanation.

19 THE WITNESS: No, because the procedure
20 does not require it.

21 BY MS. FITZPATRICK:

22 Q. Here's the idea. If Mr. Davis wants to ask
23 you why during his time for this deposition, he can go
24 ahead and do that. Until then, I want you to answer my

1 questions, and I have been remarkably patient with this
2 complete lack of ability to answer a direct question.

3 MR. DAVIS: If she feels --

4 BY MS. FITZPATRICK:

5 Q. I want very precise answers to my question,
6 and if he wants you to explain them, he can certainly do
7 that.

8 MR. DAVIS: And I'll instruct the
9 witness if she feels that an explanation is necessary,
10 she's entitled to give it after she answers yes or no or
11 says she can't answer it.

12 BY MS. FITZPATRICK:

13 Q. 19E does not identify the probability of
14 occurrence; does it?

15 A. 19E?

16 Q. And you can just stay with 19E because all
17 these questions will deal with 19E.

18 A. There is nothing in that column.

19 Q. There's nothing in the "Risk Class" column; is
20 there?

21 A. There is nothing in that column.

22 Q. There's nothing in the "Applicable Safety
23 Measure" column; is there?

24 A. There is nothing in that column.

1 Q. There's nothing in the "Other Hazards
2 Generated," column; is there?

3 A. There's nothing in that column.

4 Q. And there's nothing in the "Risk Class"
5 column; correct?

6 A. There's nothing in that column.

7 Q. And there's nothing in the assessment of
8 remaining risks; correct?

9 A. There's nothing in that column. And now may I
10 speak and explain?

11 Q. You can certainly do that when Mr. Davis
12 questions you.

13 MR. DAVIS: If you feel an explanation,
14 you're entitled.

15 BY MS. FITZPATRICK:

16 Q. GB --

17 MR. DAVIS: Is your answer over?

18 THE WITNESS: No, sir.

19 BY MS. FITZPATRICK:

20 Q. Let me make this easy, Ms. Duncan.

21 MR. DAVIS: No. We're not answering the
22 next question until you let her finish.

23 MS. FITZPATRICK: Fine. Don't answer
24 the question. I'll create a record where there are no

1 answers and you've instructed the witness not to answer.

2 That's completely fine.

3 MR. DAVIS: No, we're not going forward.

4 BY MS. FITZPATRICK:

5 Q. 19B, which looks like you have testified

6 previously --

7 MR. DAVIS: Let's go off the record.

8 MS. FITZPATRICK: I'm not going off the

9 record.

10 MR. DAVIS: We're not going forward with

11 anymore questions. We're not going -- I'm not going to

12 let you ask questions until you let her answer.

13 MS. FITZPATRICK: Call the Judge.

14 MR. DAVIS: Let her finish.

15 MR. COMBS: You want to call the Judge

16 and say you're screaming at the witness, you're on your

17 own.

18 MS. FITZPATRICK: You're darn right

19 we're going to.

20 THE WITNESS: I would answer if you --

21 MS. FITZPATRICK: -- describe why a

22 college-educated woman can't answer a question that's

23 five words long because she doesn't understand it. I --

24 I'm fairly sure Judge Goodwin would have little to no

1 patience for what is going on in this room today, and he
2 will have little to no patience when this happens on the
3 stand, believe me. I'm not ready to take a break. I'm
4 going to keep going.

5 MR. DAVIS: No, we're taking a break,
6 but --

7 THE WITNESS: It's a logical break. Put
8 that on the record.

9 MR. DAVIS: Let the record reflect she
10 was in the middle of an answer and she was not allowed to
11 finish the answer.

12 (Whereupon, a recess was taken from
13 5:27 p.m. to 5:36 p.m.)

14 MR. DAVIS: As soon as we got off the
15 record, the witness explained to me that one of the times
16 that she was being interrupted a few minutes ago, she was
17 actually trying to correct one of her answers, so I'd like
18 for her to be able to finish making that correction.

19 MS. FITZPATRICK: You can feel free to
20 ask her anything she wants.

21 MR. DAVIS: No, she's entitled to finish
22 her correction she was making.

23 MS. FITZPATRICK: You can put it on the
24 record later. It's not going to count on my time right

1 now.

2 MR. DAVIS: Well, it doesn't have to
3 count. I'll give you an extra couple minutes. Let her
4 finish her answer.

5 MS. FITZPATRICK: Okay. Go ahead and
6 change your answer.

7 THE WITNESS: It isn't so much a change,
8 that I have an omission. And I apologize, I should have
9 been looking with my magnifying glass because this is a
10 very gray document, and what I meant to include in the
11 19 -- under 19, which is "Lack of Quantitative
12 Properties," and A is "Mechanical Properties." You see it
13 first starts out with "Needles," and then the subset, they
14 go to "Mesh," and that's why it's AB, and that's what I
15 was trying to explain.

16 And so the ABA is tensile strength, and what
17 they looked at there was a potential failure of tensile
18 strength, and they have categorized it as probable --
19 probability of occurrence, and then "Risk Class," they
20 have a zero, and then for "Other Hazards Generated," they
21 have a "No," and again, a zero for "Risk Class," and
22 acceptable risk in the category of "Assessment of
23 Remaining Risk."

24 So when I was going through the columns,

1 before, I had neglected to include that one because I was
2 jumping to the -- from 16 to 19, and that was why I
3 omitted that one.

4 And I was -- I apologize if I disturbed you.
5 I was trying to explain that this is not a classic FMEA.
6 If you see this risk analysis, EN 1441, they are using the
7 list hazards that are provided in that standard as a
8 memory aid, and that's how they were doing this, and if
9 you go to the procedure, it explains why they don't
10 continue to fill in the columns. I didn't mean to upset
11 you by trying to answer you completely.

12 BY MS. FITZPATRICK:

13 Q. What's the difference between tensile strength
14 and strength of mesh?

15 A. Tensile strength and what?

16 Q. Strength of mesh?

17 A. Can you help me? Where do you see that?

18 Q. Well, you've cited 19ABA tensile strength as
19 somehow being related to degradation, and you've also
20 cited 19E, which is strength of mesh vivo/vitro as part of
21 degradation.

22 What is the difference between them?

23 A. If you look at the Category 19, if you
24 consider that as a header, you notice there's nothing

1 filled out in that, either, because it's subsets.

2 So 19 is lack of quantitative properties, and
3 they subcategorize lack of quantitative properties, and
4 in 16, they're talking about loss of mechanical integrity,
5 and that is different from lack of quantitative
6 properties.

7 Q. 19 is lack of quantitative properties?

8 A. Yes, ma'am.

9 Q. You agree with me that 19A deals with the
10 mechanical properties; correct?

11 A. It's a subset, yes, mechanical properties.

12 Q. And 19AB is, again, another subset of
13 mechanical properties that is mesh; correct?

14 A. AB, yes.

15 Q. And 19ABA is yet another subset dealing with
16 tensile strength of the mesh; correct?

17 A. ABA deals with tensile strength of the mesh.

18 Q. My question is, what is the difference between
19 tensile strength of the mesh and 19E, the strength of the
20 mesh?

21 A. They're talking there of strength of mesh
22 in vivo/in vitro, so they're considering it there, as well
23 as above, because they would have to have a baseline to
24 consider either one. So you have to consider what is the

1 tensile strength of the mesh, and then would there be
2 differences in vivo/in vitro, and that's why they've
3 identified that as not imaginable.

4 So they have considered degradation as -- in
5 that context.

6 Q. Does 19E deal with degradation?

7 A. Strength of mesh in vivo/in vitro, I
8 understood that to mean that they were considering whether
9 the strength of the mesh was altered in vivo or in vitro.
10 That could also include shelf-life aging, for example.

11 Q. And 19ABA, tensile strength deals with changes
12 in the tensile strength of the mesh when implanted; right?

13 A. A -- excuse me, ABA?

14 Q. Yep, 19ABA.

15 A. 19ABA is dealing with tensile strength and
16 whether or not that would be a failure mode. Because in
17 that column there, it's four over, in 19A -- ABA, tensile
18 strength, that would be -- they classified that as a
19 probable failure mode.

20 Q. But my only question is, what is the
21 difference between the failure mode associated with
22 tensile strength and the failure mode that is associated
23 with the strength of mesh? What is different about those?

24 A. They are --

1 Q. If you know?

2 A. They would be a property. Tensile strength is
3 a -- has a quantitative standard associated with measuring
4 it. So T and E is a particular method of measuring mesh
5 strength. So then it would be considering whether
6 strength of mesh in vivo/in vitro is also affected. So
7 they would go back to consider tensile strength of mesh
8 in vivo/in vitro.

9 Q. And I will be very honest -- and maybe it's
10 late in the day -- I am so highly confused with what you
11 just said.

12 You'll agree with me that 19ABA deals with a
13 possible failure mode of loss of tensile strength; right?

14 A. May I please --

15 Q. Yeah, please do.

16 A. When I first started trying to read this, I
17 had to put myself back in time, and I had to look at their
18 procedure, and I had to pull out EN 1441, and I had to
19 have all three documents together to begin to understand
20 how these engineers at that time were trying to assess the
21 hazards associated with the product. It is not something
22 you can do just looking at a document like this. You have
23 to have the procedure and the standard to understand the
24 document.

1 Q. My only question was, does 19ABA deal with the
2 possible failure mode of loss of tensile strength? Is it
3 or not?

4 A. It's a baseline that you would need to know in
5 order to evaluate it. So that's part of the issue. You
6 have to have -- you have to consider both. The tensile
7 strength -- is it possible that the tensile strength could
8 have a short or marginal type of failure? And they said
9 probable, and then they scored it, and then they said the
10 risk was acceptable.

11 And then when you go down and you look at
12 strength of mesh in vivo/in vitro, is it adequate for its
13 intended use in vivo and in vitro, meaning when you put it
14 in and when it's implanted? And so that's what they were
15 considering, was the strength adequate in that category?
16 That's the way you have -- you have to get the document
17 and look at the procedure and the standard to make sense
18 of this.

19 Q. I will be very honest, your explanation
20 doesn't make any sense to me, but I'm not going to belabor
21 it at this point in time.

22 A. Well, that's the best I can do with a German
23 document.

24 Q. Does the word "degradation" appear on this

1 document?

2 A. The word "degradation" does not appear on this
3 document.

4 Q. Is there anything on this document that deals
5 with the inability to remove mesh once it's been
6 implanted?

7 A. Well, if you look at 13A and B, "Complication
8 Rate Higher Than Standard Procedures," they're indicating,
9 "See clinical risks." That's where they direct you. So
10 one of the considerations I would have, as I'm reading
11 this document from my background, is the complication rate
12 would be included in the types of complications from the
13 product. That's the -- that's one of the ways that they
14 would look at this.

15 And then if you look at Number 15,
16 "Insufficient warning of adverse reactions," they are
17 also saying, "See clinical risk." They're directing you
18 to a different document because this is an engineering
19 document and they've isolated the clinical risk elsewhere.

20 Q. Well, with all due respect, Ms. Duncan, I
21 think you're reading it wrong. Because if you go to
22 subsection 28 on this document, that's the clinical risk.
23 It's not a separate document, it's a separate line item
24 with subsections on this document.

1 A. Well -- but this is also backed up by the
2 other clinical risk documents that would have been
3 available to the team at the time. That's where they got
4 their probabilities.

5 Q. Okay. Well, let me ask you this -- 13AB, "See
6 28 clinical risks." What you said to me is, "They're
7 directing you to a different document because this is an
8 engineering document and they've isolated the clinical
9 risk elsewhere." That was the answer that you've given
10 me.

11 So do you believe that 13AB where it says,
12 "See 28 clinical risks," they're directing me to a
13 different document, or do you believe that they're
14 directing me to subsection 28 of this document that's
15 called, "Clinical risks"?

16 A. These clinical risks that they have identified
17 have -- I probably didn't speak clearly. 28 is the line
18 items, and they have, let's call it, derived the
19 probability of occurrence and the failure modes about
20 clinical risks from clinical information that they hadn't
21 had.

22 Q. 13AB, where are they directing me? Are they
23 directing me to a totally separate document or are they
24 directing me to --

1 A. I explained. 28, down below. And as you see,
2 they're talking about info and IFU training. So these
3 other documents would have to be reviewed, too, as part of
4 looking at this document. This is how you go about a
5 hazard analysis, you reference additional documentation.
6 So that's what I meant by that.

7 Q. You know, when we're talking about precision,
8 I want to make sure that we're precise here.

9 What you said to me, for example, looking
10 at Number -- let's go with Number 15, "Insufficient
11 warning of adverse reactions, only product related."

12 Do you see that?

13 A. Yes, "See 28 clinical risks."

14 Q. Okay. And what you said to me, "That means
15 they're directing me to a different document because this
16 is an engineering document and they've isolated the
17 clinical risk elsewhere."

18 What document do you believe they're directing
19 me to here?

20 A. I'm sorry, I misspoke. 28 is the line item
21 for clinical risks. And then when you look at the column
22 called, "Applicable safety measure," that is where they're
23 directing you to the other clinical documentation, such as
24 the IFU, training of user. Restricted marketing is their

1 term, because that's the way they -- we would call it --
2 the FDA would call it prescription. They call it
3 restricted. Training, IFU training, patient consents, and
4 patient consents.

5 Q. Apart from the IFU, what other documents are
6 identified for me here that I can go and look at for these
7 clinical effects?

8 A. Well, I would presume where they're talking
9 about restricted marking, that would be their regulatory
10 applications, and --

11 Q. Did you look at that?

12 A. I know that as a part of the technical files,
13 you describe the intended use and who can use the product.
14 So that's what they mean by restricted use and the IFU and
15 the training of the users. That's the documents I was
16 referring to.

17 Q. Okay. Show me where in this clinical risks it
18 deals with complications arising from attempted removal of
19 the product.

20 A. Again, I would have to point out that that was
21 not an input requirement. So the closest we have as a
22 hazard is complications from use, "Complication rate
23 higher than standard procedures. See clinical risks." So
24 if they were to start to see higher clinical risk

1 occurrences and determine that it had become common to
2 remove the product, that would become a new input
3 requirement to be considered.

4 Q. But you agree with me, it's not on here as --

5 A. I don't see the exact wording you're looking
6 for.

7 Q. Okay. Rejection, the body's rejection of the
8 device.

9 Do you see that on here?

10 A. Ma'am, again, it is not part of the input
11 requirements. Rejection is a specific term for rejecting
12 tissue. Medical device companies don't typically refer to
13 rejection in that context.

14 Q. Okay. Now --

15 A. We would consider it incompat- --
16 biocompatibility failure, not rejection. It's not our
17 terminology.

18 Q. It's not your terminology, but you agree that
19 Ethicon at least used that terminology --

20 A. No, ma'am. I believe that he was repeating
21 words that the doctors were using, and it was their fear.

22 Q. But you agree that the word "rejection"
23 appears in this document that I showed you?

24 A. It was a fear, yes, ma'am.

1 Q. And it was written by Ethicon; correct?

2 A. The report was written by Ethicon.

3 Q. And identified as a main concern; right?

4 A. As a fear, yes, ma'am.

5 Q. And it's not in here? It's not in Exhibit,
6 whatever we're on now, 18?

7 MR. DAVIS: Object to form.

8 THE WITNESS: Other bio-
9 incompatibilities in Number 9 would be a -- and also
10 allergical effects. And perhaps you could include
11 teratogenicity, or rather that's a second generation. So
12 the closest we would come would be the allergical effects
13 and other bioincompatibilities.

14 And as you see, they have identified that as
15 not applicable because other bioincompatibilities, such as
16 rejection, as you're suggesting, is not part of the normal
17 considerations for synthetic materials. The allergic
18 effect would be, and they send you to Number 5 where they
19 have conducted biocompatibility testing, and it is shown
20 here as the failure would be very rare.

21 BY MS. FITZPATRICK:

22 Q. Now, do you remember when we were talking
23 about this document before, and I'm not sure what number
24 it was, but I was asking you about the erosions that were

1 introduced -- or discussed here on page 5?

2 A. You're speaking of the document that refers to
3 the repair of prolapse?

4 Q. Yes, that's the one.

5 A. And where do you want me to look?

6 Q. I want you to look on page 5 of that document.

7 Do you remember when we were talking about
8 mesh eroding into the bladder and the rectum?

9 MR. DAVIS: Object to the form.

10 THE WITNESS: We discussed this page.

11 BY MS. FITZPATRICK:

12 Q. Okay. And do you recall -- I can go back and
13 find it for you if you don't remember, but do you remember
14 I asked you whether that's something that should be
15 included in an FMEA, and you didn't believe that it should
16 be?

17 A. A failure mode effects analysis directed to
18 the failure of the mesh would probably not include this as
19 a failure mode. A risk analysis document might.

20 Q. Okay. So a risk analysis document would
21 include more than the FMEA; is that what you're saying?

22 A. Different, not more.

23 Q. And you'll agree with me that some of these
24 major concerns, such as erosion, did actually appear on

1 this design review; correct?

2 A. Do you want to direct me to the line you're
3 speaking?

4 Q. Sure. I am talking about 28L, M, and N, as in
5 Nancy.

6 A. Okay. Postoperative erosion of urethra.

7 And your question?

8 Q. Do you agree with me that in this design
9 review document, at 28L, M, and N, it talks about the
10 potential of erosion?

11 A. Yes, ma'am.

12 Q. Now, who's the user?

13 A. The user would -- I believe in this
14 circumstance, would be the patient.

15 Q. Okay. So in this document, it identifies
16 what's considered the source of the hazard; correct?

17 A. That's correct.

18 Q. And so Ethicon here identifies patients as the
19 source of postoperative erosion of the urethra; correct?

20 A. I think that that's contextual. They're
21 trying to say that certain patients may have it; others
22 may not. It's not a -- the source is not by the surgeon
23 and not by the manufacturer. So the third option would be
24 the user or no one. So it's not imaginable, user,

1 surgeon, or manufacturer. That's their four choices, or
2 not applicable.

3 Q. Postoperative erosion of the bladder is not
4 attributable to the user, but it's attributable to
5 something else called a standard procedure; correct?

6 A. Ma'am, I can't speak to that. I can tell you
7 what documents say, but I don't know the cause and effect
8 of erosion. I can read what people have written, but I
9 don't know it personally.

10 Q. Okay. The source that's identified for
11 postoperative erosion into the bladder is a standard
12 procedure; correct?

13 A. Right.

14 Q. What is standard procedure?

15 A. I believe what they're speaking of here
16 is that the standard procedure would -- could be the
17 source of this postoperative erosion, so it's kind of a
18 hybrid. They're not saying the surgeon did it; but when
19 you use a standard procedure, that could be the source of
20 a potential erosion. In other words, that's a known
21 potential side effect of the procedure.

22 Q. And then we go to another erosion, which is
23 erosion to the vagina, and we've got now another source of
24 delayed healing caused by patient or surgeon; right?

1 A. Yes. Yes.

2 Q. Okay. So each different type of erosion
3 that's identified has a different source here; correct?

4 A. Let's see. I believe that's what they were
5 trying to communicate.

6 Q. Okay. And I'm particularly interested in the
7 postoperative erosion of the vagina. It says, "Acceptable
8 as it is equivalent to standard procedures and not product
9 specific."

10 What standard procedures are they referring to
11 there?

12 A. I would have to speculate, ma'am. I don't
13 know -- where they're saying, "Acceptable as equivalent to
14 standard procedures," I believe they're speaking of the
15 alternative procedures without mesh, but that is my
16 conjecture. I don't have their source of that particular
17 assessment of remaining risks. I don't know where they
18 got that statement from.

19 Q. So you don't know what that is; is that right?

20 A. Equivalent to standard procedures, I believe
21 they mean alternative procedures because they've talked
22 about standard procedure elsewhere.

23 Q. Okay. Well, what if -- let's hypothetically
24 assume your experts have said -- other experts for Ethicon

1 have said that you can't have an erosion without mesh.

2 Then you agree with me that this assessment of remaining
3 risk can't be equivalent to non-mesh procedures; right?

4 MR. DAVIS: Object to the form.

5 THE WITNESS: Actually, I couldn't speak
6 to that because postoperative erosion of the vagina, I
7 don't know in this context or in general if other tissues
8 or other procedures such as -- well, I couldn't even say
9 because I'm not -- two reasons; one, I don't know if other
10 procedures have reported erosion of the vagina.

11 It's my understanding that the vagina can thin
12 and erode as a result of aging, but I don't know -- in
13 this case, I believe what they're speaking of was
14 equivalence to other procedures. So I can't speak to your
15 question.

16 BY MS. FITZPATRICK:

17 Q. So you just don't know. It's not in your
18 wheelhouse or your area of expertise here; right?

19 A. I will agree, it's not in my wheelhouse.

20 Q. Okay. Can you show me on this document
21 where -- this design review, Ethicon looked at the
22 possibility of mesh fraying as a hazard, if they did at
23 all?

24 A. Well, first I would take you back to loss of

1 mechanical integrity, Number 16. So they considered that
2 with respect to the material properties.

3 Q. And that's the one that directs us to 19A;
4 right?

5 A. 19A -- ABA. So if fraying affected tensile
6 strength, we might see an effect on the strength of mesh.

7 And then also, if you look at C, there's color
8 and appearance, and under C -- CB, they have mesh
9 appearance, and that would be fraying, inclusive of that,
10 if it started to look peculiar, I guess.

11 But as I understand it, fraying is actually an
12 ex vivo condition where the material is fraying as a part
13 of the surgical procedure. So just let me look for a
14 second for functional equality procedures. Again, I would
15 say loss of mechanical integrity is the primary category.
16 Erroneous mechanical damage, that Number 17, I believe
17 that's encompassing of the question of fraying. I think
18 that's -- that encompasses that question.

19 These -- as I said, these memory reminders are
20 out of EN 1441, so they're rather imprecise. You have to
21 categorize a lot of things under the category.

22 Q. Okay. Two more questions about this document.

23 Where on this document does it identify mesh
24 twisting as a potential in the design review?

1 A. Just a minute.

2 Q. Let me ask again.

3 Where in this document for the design review
4 does it identify mesh twisting as a potential hazard?

5 A. One of the considerations would be the
6 erroneous mechanical damage. So if it was twisted, it
7 would be mechanically damaged. In other words, it's
8 supposed to be flat, and if it's twisted, it wouldn't be
9 flat. You could also look at 13F, not manageable with
10 instruments.

11 So these are general characteristics that
12 would incorporate the issue of twisting. So if they had
13 considered twisting to be an issue, they would have
14 probably put it under these categories.

15 Q. And what does -- one last question on this.

16 A. Just a minute. I want to look at one more
17 thing here.

18 I want to make sure it's not covered in --
19 well, in the clinical 28, I would also believe that C,
20 overtensioning of the tape -- some of the documents I
21 recall reading were suggesting that the twisting can
22 occur when the physician is pulling it too hard, and
23 particularly handling it out of the packaging, but I --
24 it's difficult to discern here whether they were

1 speaking of an issue with -- in the surgical procedure or
2 as a part of the packaging and delivery, okay? So
3 twisting can occur, as I understand it, in either
4 circumstance.

5 Q. Okay. One more question on not imaginable.
6 Does that mean it can't happen, or does that mean Ethicon
7 doesn't know why it happens?

8 A. Well, actually, as a part of my due diligence,
9 I was curious about that term, and if you look at my
10 Exhibit 8, I've written out for you the German word. When
11 you translate unimaginable, you can find the word -- and I
12 can't pronounce it well, but it's nicht vorstellbar.

13 THE WITNESS: Do you want me to spell
14 it?

15 THE REPORTER: Yes.

16 THE WITNESS: N-I-C-H-T, second word
17 V-O-R-S-T-E-L-L-B-A-R.

18 And when you back translate that, it is the
19 word inconceivable. And so it would appear that what they
20 were trying to say was, it's inconceivable that these
21 sources that are a part of our list here would be the
22 source for those items that they have called not
23 imaginable.

24

1 BY MS. FITZPATRICK:

2 Q. Okay. So to the extent that 19E, strength of
3 mesh, deals with degradation, according to Ethicon, it is
4 inconceivable that has anything to do with the PROLENE
5 mesh itself, according to this document; is that right?

6 A. I'm sorry, I'm so tired. Would you please --

7 Q. Sure.

8 A. -- ask me the question again? I just couldn't
9 follow it all.

10 Q. 19E and 19GB you had identified for me earlier
11 as being related to the degradation, and Ethicon's
12 consideration of degradation, as part of this design
13 review in 2001; correct?

14 A. As it relates to the properties, the material
15 properties.

16 Q. Okay. And so I just want to make sure that,
17 as to 19E and 19GB, Ethicon is saying that it is
18 inconceivable that degradation could have anything to do
19 with the mesh itself; is that right?

20 A. I would direct you, it's more to the
21 mechanical properties. So the degradation word would be
22 with respect to mechanical properties. And at the point
23 in time these gentlemen were working on this document, the
24 relationship of any properties, with respect to observed

1 degradation, have not manifested themselves in any
2 mechanical changes, and I believe that's still true.

3 Q. Okay. Here's what confuses me about that:

4 19A is the subsection that deals with mechanical --

5 A. Lack of quantitative property is mechanical
6 property.

7 Q. Mechanical property?

8 A. Right.

9 Q. E and G don't deal with mechanical property.
10 That's 19A. So 19E and 19GB, which you directed me to as
11 being related to degradation, are not included in the
12 mechanical properties that you're talking about.

13 A. Well, strength of mesh. So basically,
14 what they are categorizing here, strength of mesh in
15 vivo/in vitro as a potential hazard, there's -- a change
16 of the strength of the mesh in vivo/in vitro is
17 inconceivable.

18 Q. And that's a position that -- that's what I
19 was asking. That's a position that Ethicon is taking here
20 in 2001 concerning degradation? Because you said these
21 were related to degradation.

22 A. Strength of mesh changed, degradation,
23 changing the strength of the mesh, as these gentlemen
24 understood it, I believe they meant it was inconceivable,

1 yes.

2 Q. Okay. And also the twisting that you said was
3 under 13F, not manageable with instruments?

4 A. I think that that's the category that that
5 would fall under.

6 Q. So that's also not imaginable.

7 And 19CB, which was the appearance of mesh
8 that you've related to fraying, once again, as of 2001, in
9 this particular document, Ethicon was saying that it was
10 inconceivable that the mesh and the TVT-R could fray?

11 MR. DAVIS: Object to form.

12 THE WITNESS: No, I didn't say that they
13 said it couldn't fray. 19, we were talking about -- I'm
14 sorry, 19E?

15 BY MS. FITZPATRICK:

16 Q. No, I'm sorry, 19C- -- I'd asked you about
17 fraying, and I asked you where fraying appeared--

18 A. Oh, I'm sorry.

19 Q. -- and you said it was in 19CB?

20 A. Yes, I'm sorry. I recall now. CB mesh not
21 imaginable. Color and appearance.

22 So fraying has not been established to any
23 mechanical property changes, but it obviously has a
24 peculiar appearance. And they're saying that -- in this

1 case, they were saying it was not imaginable to have a
2 color or appearance change of the mesh.

3 I'm not saying for a fact that they were
4 saying fraying couldn't happen. I'm saying that's the
5 category they would have put it under. In other words, if
6 they felt it was a consideration, I believe that fraying
7 would have come in under appearance of mesh, and that's
8 the category of not imaginable.

9 Q. Okay. And so the category that you think
10 fraying would have come under is inconceivable to Ethicon
11 as of 2001, according to this document?

12 MR. DAVIS: Object to the form.

13 THE WITNESS: I can only speculate that
14 that would be the category that fraying would have fallen
15 under, because they knew it didn't affect the tensile
16 strength -- or they knew it didn't affect the tensile
17 strength.

18 BY MS. FITZPATRICK:

19 Q. How did they know that?

20 A. The testing that had been done.

21 Q. Okay. Let me show you 18.

22 A. I thought I had 18.

23 Q. Oh, 19.

24 (Whereupon, Exhibit 19 was marked.)

1 THE REPORTER: And you wanted to know
2 the time, when we were getting close to the seven hours.
3 I have that at 6:20 we'll be at the seven hours.

4 MR. DAVIS: We can go to 6:25. We'll
5 give you five extra minutes in there.

6 BY MS. FITZPATRICK:

7 Q. Let's take a look at this April 2002 document.
8 You've reviewed this document before; right?

9 I want to direct your attention to page 877 of
10 this document.

11 MR. DAVIS: Which page, I'm sorry?

12 MS. FITZPATRICK: Bates number 877.

13 THE WITNESS: Oh, so you're not saying
14 that -- the first page?

15 BY MS. FITZPATRICK:

16 Q. No, I'm not referring to the first page.

17 A. 877, yes. All right.

18 Q. And you'll agree with me, as of April 2002,
19 Ethicon identified 11 potential new hazards for including
20 in the DDSA; correct?

21 A. No, ma'am, that's not correct.

22 Q. Okay. Tell me what they did.

23 A. First off, this document follows the procedure
24 that Ethicon required, which was to re-evaluate the DDSA

1 after two years.

2 Q. Uh-huh.

3 A. So that's why it's April 25, 2002. And the
4 person who's writing this memo is writing this memo as a
5 result of the procedure that required this re-evaluation.

6 Q. Okay.

7 A. Now, the new you're referring to, these were
8 not new hazards. The reference is to the previous
9 document --

10 Q. Okay. Let me --

11 A. -- that was attached.

12 MR. DAVIS: Let her finish the answer.

13 THE WITNESS: Sorry, that was attached
14 to the memo, okay?

15 BY MS. FITZPATRICK:

16 Q. So it says here under the first bullet,
17 "Evaluate 11 potential new hazards for inclusion in the
18 DDSA."

19 So when you say -- Ethicon says they're new
20 and you say they're not new. Which are they?

21 MR. DAVIS: Object to the form.

22 THE WITNESS: This re-evaluation, this
23 memo, which was the required procedure, indicates that the
24 July 2000 risk assessment, this one (pointing), would need

1 to be updated. So she wants to include these new hazards,
2 not previously in this document (pointing), in the DDSA.
3 So as a part of her job, she's following procedure to look
4 back two years and add these terms to what is being
5 evaluated.

6 Evaluate, that's an action items word here.
7 "Evaluate 11 potential new hazards for inclusion in the
8 DDSA." She's saying, "We need to look at whether or not
9 we want to add these new terms, that had not been previous
10 in this document, to the DDSA." And that is a requirement
11 procedure that Ethicon was following, which is a result --
12 results in this memo. They were not new hazards.

13 BY MS. FITZPATRICK:

14 Q. So when they say "11 potential new hazards,"
15 they didn't mean that?

16 MR. DAVIS: Object to the form. Asked
17 and answered.

18 THE WITNESS: As I explained, they
19 were pointing out -- this is an action item. If you
20 recognize, "evaluate" is a verb here and "reassess" in the
21 next bullet. So what she is saying is, "Our task is to
22 evaluate these terms, potential new hazards, that were not
23 included in this document" (pointing).

24 If you look at the procedure for reassessing

1 the DDSA, this was considered the original DDSA. As a
2 part of the Ethicon procedure, she was doing her job to
3 update the DDSA from the second anniversary, or close
4 thereof, to the original risk assessment document.

5 BY MS. FITZPATRICK:

6 Q. Ms. Duncan, if they're not new --

7 A. Uh-huh.

8 Q. -- why weren't they in the 2000 DDSA?

9 MR. DAVIS: Object to the form. Asked
10 and answered.

11 THE WITNESS: The -- this analysis,
12 again, was done with a different format. And you said why
13 weren't these new hazards? They weren't new hazards.
14 They weren't new hazards to Ethicon as of this date of
15 2002. They may have not been included in the risk
16 assessment that was done in 2000, but that doesn't mean
17 that they weren't known, even in 2000. They didn't make
18 it into the document.

19 BY MS. FITZPATRICK:

20 Q. So -- okay. Fair enough.

21 If Ethicon knew about these 11 what they call
22 potential new hazards as of 2000, you'll agree with --
23 July 2000, they didn't include them in the risk
24 assessment; correct?

1 A. Ma'am, you're mischaracterizing her statement
2 here. She says, "Evaluate." That's an action item.
3 "Evaluate 11 potential new hazards for inclusion in the
4 DDSA." She's asking, essentially -- she's forming the
5 task, "Do we take these bullets and add them into a new
6 DDSA?" They were not new hazards to Ethicon, and I think
7 I covered that in my report.

8 Q. So they're old hazards that for whatever
9 reason didn't make it into the July 2000 DDSA; is that
10 right?

11 MR. DAVIS: Object to the form.

12 BY MS. FITZPATRICK:

13 Q. They're not there; right? I mean, she says
14 they're not there.

15 A. It's not exactly accurate to say they weren't
16 addressed because there are crossovers here. When you
17 look -- realize, this is a procedural FMEA. This is a
18 usability FMEA.

19 So one of the things we're looking at, for
20 example, is preparing for the surgical procedure. So if
21 you look at that category, we'd have to go across and see
22 if a particular failure mode is there, and the same thing,
23 of penetration of tissues.

24 I know you're pressed for time, so I won't

1 belabor the point, but with each of these categories, we
2 would need to go back into the document and see how they
3 were addressed. I don't want to say they weren't
4 addressed at all.

5 Q. Well, you don't have to because she says --
6 and I'm reading this in black and white, so I'm not sure
7 what I'm missing here -- "Complaint categories not
8 identified in the July 2000 risk assessment and are as
9 follows."

10 So she's saying they're not identified in the
11 July 2000 risk assessment. Are you saying she's wrong,
12 that they were identified in here?

13 A. I'm saying these terms, these terms, the
14 bullet terms --

15 Q. Right.

16 A. -- may not have been in this risk assessment,
17 but that doesn't mean that the hazards had not been
18 considered. She is talking in terms of complaint
19 categories not identified in July 2000.

20 That -- the categories in this list and how
21 they assessed risk in this document may not have been word
22 for word or item for item, and what she's saying is, to
23 make it consistent with what we know relative to this, we
24 should evaluate whether or not these terms should be added

1 to our DDSA so that we can better categorize these
2 potential new hazards, okay?

3 Again, these are not new, as I've pointed out
4 in my report, and she was doing the job of reassessing the
5 DDSA in its second anniversary, and that's considered --
6 that in the procedure is called out as an interim
7 assessment. So that's a requirement by Ethicon to do what
8 she did here.

9 Q. Okay. Let me ask you this.

10 The risk assessment was completed by Medscand
11 Medical in July 2000; correct?

12 A. Yes. Was used to complete this re-evaluation.

13 Q. Right. And you've looked at all of the
14 documents that were available from Ethicon concerning the
15 risk assessment that was completed by Medscand Medical in
16 July 2000; correct?

17 A. I looked at this document. I don't know if
18 there were other supporting documents that I didn't see.
19 I can't say exactly.

20 Q. So I don't want to talk about hypotheticals.

21 Have you seen any documents which indicate or
22 show that these -- what she calls potential new hazards,
23 whatever you want to call them, that these 11 potential
24 new hazards were actually considered in July 2000 in the

1 risk assessment completed by Medscand Medical and rejected
2 or not included in the DDSA for whatever reason?

3 MR. DAVIS: Object to the form.

4 THE WITNESS: Let me get to my report,
5 if that's all right with you.

6 MR. DAVIS: You are at the deadline, but
7 I will allow this to finish.

8 THE WITNESS: Yes, I'm sorry for taking
9 so long. It's a lot to look at.

10 Okay. So what I believe, as I was pointing
11 out here on 21, on my report, that in --

12 BY MS. FITZPATRICK:

13 Q. Okay.

14 A. I think -- okay. These hazards -- I'm
15 looking, I'm sorry, page 22. These hazards were not new,
16 were already well known prior to 2002, and had already
17 been evaluated.

18 Q. That's my new question; where were they
19 evaluated? What is your basis of that?

20 A. I go on and explain here as we go forward.
21 "As early as June 2000, a panel of 17 surgeons
22 experienced in the use of TVT discussed the then-known
23 hazards associated with the clinical use of the TVT mesh
24 and concluded they were minimal." And Number 61 is the

1 footnote reference to the Bates numbers.

2 Q. Okay.

3 A. And that was a June panel, okay? And that
4 was June 2000.

5 Now, the revision date for this was -- for
6 this TVT Preventia document that you were pointing to that
7 was attached to the April 2002 memo, that has a July 12,
8 2000, date, and so the June panel of 17 surgeons had --
9 was virtually on top of this document's creation.

10 So then we go on and we read the review of
11 complaints for the first 10 months of 2005, found again
12 only relatively few reports of the same types of
13 complaints found in the earlier reports discussed above.

14 So basically -- I skipped a sentence there.
15 And it goes over to 23. "In addition, in December 2001,
16 Ethicon's medical director, Martin Weisberg, M.D., had
17 yet again assessed the then known risks associated with
18 the product." And that's Footnote 62.

19 Q. So let me -- I don't mean to cut you off.
20 I know we're --

21 A. Yeah, I know. We're short on time.

22 Q. -- running out of time. I don't want you to
23 have to read from your expert report.

24 So you don't have anything in addition to what

1 you've cited here in your expert report to supplement that
2 with; right? What you relied on, what your conclusions
3 are, are contained in the four corners of this report?

4 A. And my assessment of the procedure that govern
5 this activity. And I believe that procedure was in my
6 reliance document, but I did not footnote it.

7 Q. Can you go to 881? Just a couple more
8 questions and then we'll wrap this up.

9 MR. DAVIS: We'll allow a couple more.

10 MS. FITZPATRICK: What's that?

11 MR. DAVIS: I said, we'll allow a couple
12 more, wrap it up.

13 BY MS. FITZPATRICK:

14 Q. See this attachment? I don't know whether
15 it's 1 or I, this one right here (pointing), medically
16 related complaints?

17 A. Uh-huh. Yes.

18 Q. So you'll see that a number of these,
19 including vaginal extrusion, erosion urethral, perforation
20 by mesh, infection, post-op complication, vaginal
21 incision, and urethral tear, have not been listed in the
22 DDSA; correct?

23 A. In the Preventia document, I could not find
24 them with that terminology, no.

1 Q. Okay. And it actually states here that it was
2 not listed in the DDSA; correct?

3 A. Listed in -- there's a yes -- yeses and nos in
4 the second column.

5 Q. Right. And vaginal extrusion, erosion
6 urethral, perforation by mesh, infection, post-op
7 complication, vaginal incision, and urethral tear, those
8 are all nos?

9 A. I believe that's what the memo says, yes.

10 Q. Okay. And so because they're nos, there's
11 been no analysis done on the severity, the frequency, or
12 the RPN of those potential complaint categories; right?

13 MR. DAVIS: Objection to form.

14 THE WITNESS: I can't say that no
15 assessment was done because I thought -- frankly, I
16 thought we saw some of these over in -- the other analysis
17 that we were just looking at referenced 18.

18 MR. DAVIS: Exhibit 18?

19 THE WITNESS: Exhibit 18.

20 BY MS. FITZPATRICK:

21 Q. All right. Well, whoever wrote Exhibit
22 Number 19 either didn't know about or didn't include
23 whatever information you think is relevant from Exhibit 18
24 in here; correct? It says, for example, "Vaginal

1 extrusion, severity to be determined."

2 MR. DAVIS: Object to the form.

3 BY MS. FITZPATRICK:

4 Q. "TBD"; right?

5 A. Frankly, I'm a little lost in your questions
6 because they've circled around.

7 As I've said before, the Sue Meltzer memo was
8 referencing the risk analysis Preventia; okay?

9 Q. Right.

10 A. So when she's saying "Listed in the DDSA,"
11 she's speaking of this document, the -- as I said before,
12 these risks -- these hazards, I should say, these hazards
13 were already known to Ethicon.

14 Q. Okay. So they're known to Ethicon, they
15 weren't listed in the DDSA --

16 A. The Preventia document.

17 Q. Right, which is what they call the DDSA. And
18 it says here they have an action item or an action column
19 associated with the medically related complaints here. So
20 vaginal extrusion, the action was to assess the hazard?

21 A. Yes.

22 Q. The erosion urethral, the action was to assess
23 the hazard?

24 A. Yes.

1 Q. Perforation by mesh, the action was to assess
2 the hazard?

3 A. Yes.

4 Q. Infection, the asset -- action was to assess
5 the hazard?

6 A. That is correct. You're reading the column
7 correctly.

8 Q. Vaginal incision and urethral tears, both were
9 to assess the hazard; correct?

10 A. Yes.

11 Q. Have you ever seen this document where the
12 hazard has been assessed and the whole chart is filled
13 out?

14 A. This document was created in 2002.

15 Q. Fair enough.

16 A. It wouldn't --

17 Q. Fair enough. Have you seen a later draft of
18 this where those actions have been undertaken and the
19 chart is completely filled out instead of having "NA" or
20 "TBD," that it has been a completed assessment of the
21 hazard by Ethicon?

22 A. I believe those hazard assessments were done
23 in a different document.

24 Q. And what document is that?

1 A. I believe they -- let me see.

2 MR. DAVIS: I'll let her answer this
3 question --

4 MS. FITZPATRICK: Okay. There's one
5 more. If she can tell me what that document is, I'll move
6 on from this.

7 THE WITNESS: Well, there was overlap,
8 so the hazards in the memo were partially covered by the
9 Anhang document.

10 BY MS. FITZPATRICK:

11 Q. Which one is that?

12 A. This is your Exhibit 18.

13 Q. The one that predates this?

14 A. They were also assessed as a part of
15 Dr. Weisberg's memo in December 2001, which was following
16 this.

17 Q. This is April 2002. The Weisberg memo
18 predates this; right?

19 A. I'm sorry, it followed this Anhang; it didn't
20 follow -- you're right. It didn't follow Sue Meltzer's
21 document; it followed the -- let's see, it followed the
22 Anhang document, 18, in reference -- Exhibit 18.

23 Q. Okay.

24 A. This is the signed one, yes.

1 Q. Okay. Let me -- one last question that I
2 have, and I will --

3 A. But may I also finish the --

4 Q. Note that I was trying to wrap it up here.

5 A. I'm sorry, but I just wanted to finish.

6 Q. Uh-huh.

7 A. In 2005 and in 2006, there were additional
8 reviews. In 2006, they conducted a comprehensive review
9 of the TVT complaints for the entire period from 2003,
10 which was a year following the memo, through January 2006,
11 and they assessed -- this is where they assessed the
12 hazards, I believe she referred to them as. That's when
13 they were formally assessed in the -- 2006, in that
14 document. That's the comprehensive review document, and
15 the footnote for that is 64.

16 Q. Footnote 64 on that, okay.

17 Ms. Wilson -- I'm sorry, Ms. Duncan. I'm
18 getting tired.

19 You state in your report that your opinions
20 are expressed to a reasonable degree of professional
21 certainty within your field of expertise.

22 What field is that?

23 A. My field of expertise is medical product
24 development and compliance.

1 MS. FITZPATRICK: That's all that I
2 have.

3 MR. DAVIS: Let me take just a couple
4 minutes. I'll go get some documents. We've got a few
5 questions.

6 (Whereupon, a recess was taken from
7 6:39 p.m. to 6:42 p.m.)

8 EXAMINATION

9 BY MR. DAVIS:

10 Q. Could you pull out your report real quickly,
11 Ms. Duncan?

12 A. Yes.

13 Q. And turn to page 23. I'm focusing now on the
14 very last part of the question and one of your answers.
15 You were, I believe, responding to Counsel's questions
16 about what were other reviews that assessed these 11
17 hazards referenced in Ms. Meltzer's memo, Exhibit --
18 whichever exhibit it was, and you got as far as 2006, I
19 believe?

20 A. Yes.

21 Q. I just want you to look at your report, and
22 look on down that page in the 2010 and 2013 time frame and
23 tell us whether or not you recall additional evaluations
24 of these types of hazards in these later years.

1 A. Yes, 2008, this was a more comprehensive risk
2 management report, and that was the type of risk
3 assessment that superseded the DDSA method. In 2010, they
4 performed another complaint review, and this was inclusive
5 from January 2008 to 2009. And then in August 2010, they
6 prepared a clinical evaluation report, and at that time,
7 the mesh device was the same. They did yet another
8 complaint review of the TVT device.

9 And in 2013, they prepared a clinical
10 evaluation report for the entire family of TVT, which
11 included reports -- which was including complaints for the
12 period from January 2010 through 2013. At that point, I
13 didn't review any more current documents.

14 Q. Okay. Could you pull out Exhibit 15?

15 A. Okay.

16 Q. It's the dog study.

17 A. Oh, uh-huh. Yes.

18 Q. Do you recall being asked a few questions
19 about this?

20 A. Yes.

21 Q. And do you recall that the focus was -- was on
22 the second page of the document in the questioning of you?
23 Do you recall that?

24 A. Yes.

1 Q. I want to turn you back to the first page.

2 A. All right.

3 Q. And direct your attention to the paragraph
4 that appears under the heading, "IV and GPC."

5 Do you see that paragraph?

6 A. Yes. Yes.

7 Q. Read that paragraph to yourself. Or tell you
8 what, just read it out loud, that paragraph.

9 A. Okay, "The gel permeation chromatography (GPC)
10 was run on PROLENE sutures explanted from dogs after seven
11 years. The GPC data was compared to data from current
12 PROLENE -- 4/0 PROLENE suture. The results indicate that
13 there was no significant difference in the molecular
14 weight between 4/0 PROLENE control and the seven-year
15 explants."

16 Q. Does -- does that have -- no significant
17 difference in molecular weight, does that have a meaning
18 to you?

19 A. Yes. It's my understanding that the molecular
20 weight, particularly the molecular weight distribution,
21 would reflect a degradation of a material. So it would
22 alter the molecular weight distribution plot.

23 Q. So by finding no significant difference, can
24 you explain whether or not there's any significant

1 degradation being found?

2 A. That would indeed mean that the molecular
3 characteristics, the chemical characteristics, have not
4 degraded.

5 Q. Okay. And now, I'd like to direct your
6 attention to Exhibit 12 for a minute. It's that one-page
7 timeline --

8 A. All right, yes.

9 Q. -- if you can find it.

10 A. Yes.

11 Q. Now, let me ask you this: Did you see the
12 standard EN 46001 listed on this timeline?

13 A. Get my magnifier again. 46001?

14 Q. Yeah, I don't see it on there. I want to see
15 if you see it on there.

16 A. No, I don't see EN 46001.

17 Q. Well, with respect to European standards, if
18 you were going to be interested in knowing what standard
19 applied back in the late 1990s, would you expect to have
20 EN 46001 on this timeline?

21 A. Well, that was the one that was applicable
22 during the auditing. And certainly through the due
23 diligence for licensing and acquisition, the audits by the
24 appropriate notified bodies were conducted to EN 46001

1 because that was the applicable standard for that product
2 in that time --

3 Q. Do you --

4 A. -- in that location.

5 Q. I'm sorry.

6 A. Yeah, sorry.

7 Q. Do you recall that Anne Wilson's report
8 asserted on page 4 that ISO 13485 defined the requirements
9 of the proper risk analysis since 1996? Take a look at
10 page 4 of her report.

11 MS. FITZPATRICK: Let me find a copy of
12 that.

13 THE WITNESS: Did you say page 6?

14 BY MR. DAVIS:

15 Q. No, page 4. Look at the last sentence -- the
16 last two sentences above the heading, "Number 2," above
17 paragraph Number 2.

18 A. Yes. So --

19 MS. FITZPATRICK: Can you hang on one
20 second?

21 THE WITNESS: Oh, sure, sure.

22 MS. FITZPATRICK: I'm trying to get a
23 copy of this and orient myself. So where are we? Page...

24 MR. DAVIS: Page 4 of Anne Wilson's

1 report, the second-to-last sentence of -- above the
2 heading, "Number 2."

3 MS. FITZPATRICK: Okay.

4 BY MR. DAVIS:

5 Q. Do you see where she states that, "ISO 13485
6 has defined the requirements for proper risk analysis
7 since 1996"?

8 Do you see where she says that?

9 A. Yes, I see where she says that. In my copy,
10 it's circled.

11 Q. Is that accurate?

12 A. Well, first -- first and foremost, 13485 does
13 not treat proper risk analysis. That's not in the context
14 of 13485. And 13485 was not actually applicable to the --
15 it was -- as I recall, it was a DIS standard. It was
16 still being proposed. D-I-S is a term -- capital D-I-S is
17 a term.

18 And it was actually the EN standard that
19 was applicable at the time she's citing, 1996 through,
20 I believe, all the way -- I think in my report, I
21 point out that it was applicable up until the ISO
22 13485:2003 was adopted by the European organizations
23 by the director.

24 Q. So I just want to make sure I got this.

1 If you're doing the type of work that you and
2 Anne Wilson were doing, how important is it to identify
3 the correct standards?

4 A. Well, we have to be able to look at the
5 document that was in effect at the time that we're
6 assessing.

7 Q. Okay. And so do I understand you correctly,
8 ISO 13485 did not become an adopted standard for your
9 industry, even in Europe, until 2003?

10 A. It was in 2003 that they -- that was the
11 cutoff point for no longer accepting EN 46001 in Europe.
12 It's still not the required standard in the United States.

13 Q. Okay. And so let me take you, then, back
14 to -- did you review documents that explained when the
15 TVT product was actually designed and developed? Can
16 you give us a time frame, a range?

17 A. I think I had that note, because I thought it
18 was a critical time.

19 In my Exhibit 8, I pointed out that TVT was
20 already in the clinic in January 1995. So the standards
21 that were -- like the ISO 13485:1996 came out some
22 long-term after that, and EN 46001 was not prescribing --
23 it was -- it was still an optional standard for use in
24 Sweden.

1 So if Sweden allowed the product to be put on
2 the market or used in the clinic under their rules, then a
3 company was not required to follow EN 46001, and Sweden
4 didn't adopt the EN standards for quite some time after
5 that.

6 Q. Okay. And so back in -- at the time the TVT
7 device was designed and developed, do you know of any
8 standard that called for doing an FMEA?

9 A. No. It would not have been applicable to a
10 device sold in Sweden for use in a clinic in 1995.

11 Q. And again, you see on page 4 of Anne Wilson's
12 report where she says that 13485 define the requirements
13 for risk analysis.

14 And I think, am I correct, you've already said
15 that that's simply wrong?

16 A. It may have -- I know it is not a document
17 that defines proper risk analysis. It may make reference
18 to doing analysis. It certainly isn't defining the risk
19 analysis. That would have been done within EN 1441.

20 And the BS, by the way, is a British adoption
21 of EN 1441. EN 1441 was a European issued standard by
22 CEN CENELEC, and it was not adopted yet in Sweden.

23 Q. Okay. You mentioned CEN. Is that C-E-N?

24 A. C-E-N.

1 Q. And CENELEC?

2 A. C-E-N-E-L-E-C.

3 Q. Now, are those two organizations that are
4 delegated under European regulations to adopt standards?

5 A. Yes, the regulations are essentially -- it's
6 actually called directives. So those countries that sign
7 onto the European Common Union and adopt the directive
8 then would, by virtue of that, adopt the standard that is
9 created by EN -- excuse me, by CEN or CENELEC, unless they
10 have their own national standard to supersede it.

11 Q. Is -- the European committee that adopted the
12 medical directive, how do they compare with the FDA? Are
13 they a European counterpart?

14 A. Roughly speaking. So the European directives
15 are, to the European Common Union, sort of an über
16 national recognized group, and then each of the countries
17 within the European Common Union would have to accept or
18 reject their directive. Once they've adopted the
19 directive, then they convert those requirements into their
20 own national requirements.

21 Q. Is the directive analogous to what we would
22 call, in the United States, regulations over here?

23 A. Yes.

24 Q. I mean, governmental-type regulations?

1 A. It's adopted by each country -- by -- through
2 the European Union.

3 Q. Okay. And so -- and I believe you said that
4 EN 1441 for risk analysis and EN 46001, those -- are those
5 industry-adopted standards or regulatory standards?

6 A. They're at the national level. They're
7 adopted at the national level. So if -- a country would
8 adopt them, and if they don't adopt them, they would have
9 to have their own equivalent one that would be recognized
10 by the European Union.

11 Q. Okay. And I notice on Exhibit 12, it's hard
12 to read, but do you see where Ms. Wilson has written in
13 the title of "ISO 13485:2003"?

14 Can you see that?

15 A. Yes, "Requirements for regulatory purposes"?

16 Q. Yeah. So, I mean, is it correct that even ISO
17 13485:2003 is a standard that is for regulatory purposes?

18 A. Yes, it exists as a form of regulation of the
19 design, development, production, quality systems, risk
20 management, et cetera, that go along with a medical device
21 being allowed to operate in the European Union.

22 Q. Was ISO 13485:2003 then adopted by CEN and
23 CENELEC?

24 A. I believe they were. They essentially

1 obsoleted the EN 46001 and adopted the ISO standard. They
2 didn't create it. International Standards Organization
3 created it, so they adopted it and made it their own.

4 Q. Now, has the FDA adopted ISO 13485?

5 A. No, sir, they do not recognize the standard.

6 Q. So the European regulators have adopted ISO
7 13485:2003, but the federal -- United States regulators
8 have not?

9 A. That's correct.

10 Q. Okay. And now, I want to speak for a moment
11 about ISO 14971, the 2007 version.

12 Do you know whether or not our FDA has
13 recognized it as a consensus standard, as applicable
14 today?

15 A. I believe that 2007 is adopted. I think
16 that's right. Can I look at my report?

17 Q. Sure. And if you have trouble finding it, I
18 can go on.

19 A. I believe I make reference to it. I can't
20 find in my report the exact date, but I believe it
21 was 2007 that they adopted. But I'm frankly getting tired
22 and I can't recall.

23 Q. That's fine. We'll move on.

24 A. Okay.

1 Q. I'm almost through.

2 Now, do you know of any standard that required
3 retrospective creation of an FMEA back in the 1990s for a
4 device that had already been designed and developed back
5 in the early 1990s?

6 A. I don't recall any standard requiring a
7 retrospective creation, no.

8 Q. And now, I understand that in the 2000s, we
9 got to the point of needing to do, you know, ongoing risk
10 assessment; is that correct?

11 A. About that time, companies were beginning to
12 say -- well, to recognize that if they hadn't done a risk
13 assessment -- well, certainly the -- in 1997, when the FDA
14 regs came out, the companies -- they were actually told by
15 FDA that the application of the revised quality system
16 regs, which included a statement in the design control to
17 do a risk analysis, they were instructed that they would
18 need to do a design control and review, which included
19 risk analysis, if they made significant changes to the
20 device or made application to FDA about a change to the
21 device.

22 Q. But what about for an existing device that was
23 not being changed?

24 A. No. If a device had been marketed -- designed

1 and then marketed prior to the effective date of the
2 revised quality system regs, then the companies would not
3 be expected to become compliant with design control until
4 they did that change or introduced a new product.

5 Q. For the purpose of marketing TVT in the United
6 States by the 1890 -- late 1990s, was there any
7 requirement for Medscand to do the Preventia risk
8 analysis?

9 A. I believe there had been some --

10 Q. And let me make sure my question is clear.

11 I'm talking about, is there any industry
12 standard requirement as opposed to an Ethicon requirement?

13 A. No, there wouldn't have been an industry
14 standard. The device was already designed, and the
15 kick-in of doing a risk analysis would have only occurred
16 for new products at that point in time.

17 Q. In 2001, when the design review was conducted
18 that we talked -- you talked about the Anhang document
19 several times today. Was there any requirement -- for
20 marketing TVT in the United States, was there any
21 regulatory or industry standard requirement for Ethicon to
22 have performed that risk analysis?

23 A. I believe Ethicon was acting proactively,
24 because at the time that their 510(k) was cleared, the

1 product had been manufactured in Europe, and so
2 FDA was not expecting products that were not under
3 the jurisdiction of FDA in their design to be
4 applicable -- to have to follow the new design
5 requirements.

6 They still had to meet GMPs, and we know that
7 Medscand had been audited to GMPs. And I believe there
8 were some additional inspections of Sorrell at that point,
9 so FDA, at some point, inspected and found them
10 acceptable.

11 Q. Do you recall Anne Wilson's report criticizing
12 the -- Ethicon's design history file for the original TVT
13 class of product?

14 MR. WALLACE: Never believe a lawyer
15 when he says he has a few questions.

16 MR. DAVIS: I'm almost done.

17 THE WITNESS: Do I recall per --

18 BY MR. DAVIS:

19 Q. Do you recall just in general -- you don't
20 need -- that one of her criticisms was a lack of
21 information in a design history file for the original TVT
22 product?

23 A. Yes. She was, as I recall, looking at
24 document compilations, what I would call a project

1 history, and criticizing that she couldn't find the
2 document she was looking for under the FDA requirements
3 for design history file.

4 Q. Prior to 2003 -- I'll just take it back to
5 that time -- do you know of any standard anywhere in the
6 world, government or industry, that required a design
7 history file?

8 A. Prior to 2003?

9 Q. Yes.

10 A. Well, the design history file kicked in when
11 the -- in the U.S. when the revised quality system regs
12 took effect in 1997.

13 Q. Okay. So let me follow up on that.

14 A. Yeah.

15 Q. So the FDA requires a design history file
16 that's -- starting in 1997?

17 A. If you designed a product in the United
18 States, it was a requirement.

19 Q. Now -- and in that connection, was there
20 any -- when the FDA did come out with that requirement,
21 was there any retrospective requirement to create a design
22 history file for products that had already been designed
23 and developed?

24 A. No.

1 Q. Okay. So separate from the FDA and its
2 requirements, were there any standards anywhere in the
3 world, prior to 2003, that required a design history file?

4 A. May have required documentation, but not a
5 design history file.

6 Q. Okay. Now, you've mentioned audits a couple
7 of times today.

8 The -- do you recall whether some of those
9 audits were performed by BSI and TUV?

10 A. At one point, Ethicon went universally over to
11 BSI. Prior to that, the TUV had been audited by TUV.

12 MS. FITZPATRICK: It's tough to get out
13 this time of night.

14 BY MR. DAVIS:

15 Q. Are these auditors organizations that
16 are authorized by the European Union to conduct
17 audits?

18 A. Yes. They are considered notified bodies,
19 and some are notified bodies and ISO registrars.

20 Q. Can you tell me, are these types of audits
21 relevant to a -- due-diligence-type reviews that you were
22 doing or that Anne Wilson was claiming to do?

23 A. I felt they were relevant in the same way that
24 I was looking at the compliance with all of the regulatory

1 requirements because quality systems are a regulatory
2 requirement.

3 And being compliant -- particularly for
4 Europe, being compliant with the quality systems is the
5 first gate in order to get a product into the European
6 Union. The second gate is examination of the technical
7 file. That is a requirement under the directives. So the
8 annexes that call out what goes into a technical file are
9 established through the medical device directive.

10 MR. DAVIS: That's all I have. Thank
11 you.

12 REEXAMINATION

13 BY MS. FITZPATRICK:

14 Q. I just have, truly, a couple questions.

15 You referenced quickly some documents from the
16 2008 time frame, a comprehensive risk management report.

17 Do you recall that in response to --

18 A. Yes.

19 Q. That wasn't a document that was specific to
20 the TVT-R mechanically-cut mesh; was it?

21 A. I can't recall at this point. I would have to
22 assume by the date, it may have included more than just
23 mechanical cut.

24 Q. And you know that document also contains

1 information concerning the TVT-O; correct?

2 A. I believe they were reviewing like what they
3 called legacy products in that document, but I'm recalling
4 from memory.

5 Q. Okay. And likewise, with the 2010 clinical
6 evaluation report, that wasn't specific to the TVT
7 retropubic mechanically-cut mesh, was it?

8 A. It was not exclusive, as I recall.

9 Q. That was -- the TVT-R mechanical cut was
10 included with other products in that; is that correct?

11 A. I believe it was a comprehensive review.

12 Q. It included other products in addition;
13 correct?

14 A. I believe that's true.

15 Q. And did you refer to a 2013 clinical
16 evaluation report, as well?

17 A. Yes.

18 Q. And again, that wasn't specific to the TVT-R
19 mechanical cut?

20 A. It wasn't exclusive, that's correct.

21 Q. And that included the entire family of the TVT
22 products in a single report; correct?

23 A. I believe it was considered a family. I don't
24 know what it may have left out, but yes.

1 MS. FITZPATRICK: That's all I have.

2 MR. DAVIS: We'll read and sign. We'll
3 just take a rough.

4 (Whereupon, the deposition concluded
5 at approximately 7:20 p.m.)

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1 STATE OF MINNESOTA)
2) ss
3 COUNTY OF ANOKA)
4

5 Be it known that I took the foregoing deposition
of ELAINE DUNCAN, on the 6th day of October, 2015, in
6 Minneapolis, Minnesota;

7 That I was then and there a notary public in and
for the County of Anoka, State of Minnesota, and that by
8 virtue thereof, I was duly authorized to administer an
oath;

9
10 That the witness was by me first duly sworn to
testify the whole truth and nothing but the truth relative
to said cause;

11
12 That the testimony of said witness was
recorded in Stenotype by myself and transcribed into
typewriting under my direction, and that the deposition is
13 a true record of the testimony given by the witness to the
best of my ability;

14
15 That I am not related to any of the parties
hereto, nor interested in the outcome of the action;

16 That the reading and signing of the deposition
by the witness and the Notice of Filing were not waived.

17
18 WITNESS MY HAND AND SEAL THIS 8TH DAY OF
OCTOBER, 2015.

19
20

BARBARA J. CAREY, RPR
Notary Public

21
22
23
24

1 CORRECTION SHEET

2 DEPOSITION OF: Elaine Duncan

REPORTED BY: Barbara J. Carey

3

4 PAGE# LINE# CORRECTION REASON

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BE IT KNOWN THAT I, the undersigned deponent, have
21 this ____ day of _____, 2015, read the within
transcript of my deposition testimony. I have made
22 _____ correction(s) (if any) to said transcript
and have stated my reason(s) for each and every correction
23 above.

24

Elaine Duncan